UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF RHODE ISLAND

IN RE LOESTRIN 24 FE ANTITRUST LITIGATION	MDL No. 13-2472
	Master File No. 1:13-md-2472-WES-PAS
THIS DOCUMENT RELATES TO: ALL ACTIONS	

OPINION AND ORDER ON SUMMARY JUDGMENT AND ORDER REGARDING MOTIONS TO EXCLUDE CERTAIN EXPERT OPINIONS

WILLIAM E. SMITH, District Judge.

With trial fast approaching, Defendants seek summary disposition of this case. The Court disagrees that issues presented may be disposed of summarily – although some issues are fairly close calls – and therefore denies Defendants' motion for summary judgment, ECF No. 842. The reasons are explained below. The Court also, for the reasons set forth below, denies the pending cross-motions for summary judgment on market power, ECF Nos. 496, 569. And finally, related to all motions for summary judgment, the Court resolves in this order several of the pending Daubert motions.

I. Background

Warner Chilcott launched Loestrin 24 ("Loestrin"), an oral contraceptive, in 2006 after the Food and Drug Administration ("FDA") approved its New Drug Application ("NDA"); Warner Chilcott then listed its new drug in the FDA's Orange Book as covered by

U.S. Patent No. 5,552,394 ("´394 patent"). See Pls.' Statement of Disputed Facts ("PSOF") ¶¶ 1, 48-51, ECF No. 979. The company sold Loestrin until 2013, when it discontinued its manufacture and switched to making the drug Minastrin 24 ("Minastrin") under a new NDA. See id. ¶¶ 2-3, 192. Minastrin had the same active ingredients and dosing schedule, but Warner Chilcott added labeling informing customers that the pills could be chewed and added spearmint to the inactive pills to distinguish it from Loestrin. See id. ¶¶ 2, 192.

An AB-rated generic version of Loestrin was not marketed until 2014, despite attempts by three separate companies to introduce one sooner. Id. ¶¶ 52, 58, 62, 110. Pursuant to the protocol envisioned by the Hatch-Waxman Act, Warner Chilcott sued all three for infringing the ´394 patent. Id. ¶¶ 52, 58, 62. These suits ended in settlements in which Warner Chilcott allegedly compensated the generic manufacturers to refrain from entry until a specific date, six months before the ´394 patent expired. See id. ¶¶ 52-53, 58, 60, 62, 65. Since the first generic entered in 2014, six additional Loestrin generics have come to market, as have multiple Minastrin generics. Id. ¶¶ 110, 209, 212.

Plaintiffs' case — detailed in this Court's most recent motion-to-dismiss decision, with which the Court assumes familiarity — is simply that generics should have been available for them to purchase earlier. See In re Loestrin 24 Fe Antitrust

Litig., 261 F. Supp. 3d 307, 324-25 (D.R.I. 2017) ("Loestrin II"). And indeed they would have been but for Defendants' allegedly anticompetitive conduct, including: protecting Loestrin with a patent Warner Chilcott knew was invalid; filing sham patent infringement lawsuits against prospective generic entrants; settling those suits to split monopoly profits; and formulating a new drug (Minastrin) only to limit generic substitution. Id.

II. Discussion

The Court has before it three motions for summary judgment, and the standard necessary to resolve these motions is well established. Summary judgment is appropriate when "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56. The nonmovant defeats a summary-judgment motion by marshaling evidence that would allow a jury to decide a material fact in its favor. Theriault v. Genesis HealthCare LLC, 890 F.3d 342, 348 (1st Cir. 2018). Although given the benefit of all reasonable inferences, nonmovants may not rely on "conclusory allegations, improbable inferences, and unsupported speculation." Mulloy v. Acushnet Co., 460 F.3d 141, 145 (1st Cir. 2006) (citation omitted). Where appropriate, in a case like this one, "the plaintiffs must present a 'genuinely disputed issue of material fact' as to the elements of the rule of reason analysis; only then will the case go to a jury." In re Namenda Direct Purchaser

Antitrust Litig., 331 F. Supp. 3d 152, 198 (S.D.N.Y. 2018) ("Namenda I") (quoting In re Wellbutrin XL Antitrust Litig., 133 F. Supp. 3d 734, 754 (E.D. Pa. 2015), aff'd sub nom. In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class, 868 F.3d 132 (3d Cir. 2017), judgment entered sub nom. In re Wellbutrin XL Antitrust Litig., No. 15 Civ. 2875, 2017 WL 3529114 (3d Cir. Aug. 9, 2017) ("Wellbutrin XL I")).

Here, there are many Daubert motions standing between the Court and the evidence it may consider in deciding these motions. These need to be resolved in order to consider (or not) the proffered expert opinions in support of, and in opposition to, summary judgment. See Namenda I, 331 F. Supp. 3d at 168 ("If the expert testimony is excluded as inadmissible, the court must make the summary judgment determination without that evidence.") (citation omitted).

In its role as gatekeeper, the Court "may exercise wide discretion to admit or exclude such testimony consistent with its obligation to ensure that the jury receives only relevant and reliable expert evidence." Alifax Holding SpA v. Alcor Sci. Inc., 387 F. Supp. 3d 170, 173 (D.R.I. 2019). Rule 702 of the Federal Rules of Evidence provides that a qualified witness may testify if "the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; [] the testimony is based on

sufficient facts or data; [] the testimony is the product of reliable principles and methods; [] and the expert has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702.

Experts, of course, do not have "carte blanche" to express any opinion, no matter its limitations or lawfulness. Ruiz-Troche v. Pepsi Cola of Puerto Rico Bottling Co., 161 F.3d 77, 80 (1st Cir. 1998). The Supreme Court has interpreted Rule 702 to direct "the trial judge to evaluate an expert's proposed testimony for both reliability and relevance prior to admitting it." Id. (citing Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 589–95 (1993)). This "flexible inquiry into the overall reliability of a proffered expert's methodology" involves review of such factors as "the verifiability of the expert's theory or technique, the error rate inherent therein, whether the theory or technique has been published and/or subjected to peer review, and its level of acceptance within the scientific community." Id. at 81. Put simply, the expert's opinion and testimony should "impart[] 'scientific knowledge' rather than guesswork." Id. (quoting Daubert, 509 U.S. at 592). The Court will rule on the relevant Daubert motions as necessary to decide the summary judgment motions.

With these guideposts in mind, the Court first turns to the threshold issue of market power, then moves on to the merits issues, and finally state law and damages issues.

A. Market Power Summary Judgment[1]

Market power is a hotly contested, threshold issue. See Flovac, Inc. v. Airvac, Inc., 817 F.3d 849, 853 (1st Cir. 2016). Plaintiffs' Sherman Act claims require them to show Defendants possessed market power, "meaning the power to control prices or exclude competition." E. Food Servs., Inc. v. Pontifical Catholic Univ. Servs. Ass'n, Inc., 357 F.3d 1, 5 (1st Cir. 2004); United States v. E. I. du Pont de Nemours & Co., 351 U.S. 377, 391 (1956); see also 15 U.S.C. §§ 1-2. Section 2 requires a greater degree of market power — referred to as monopoly power — than Section 1. Eastman Kodak Co. v. Image Tech. Servs., Inc., 504 U.S. 451, 481 (1992).

To be frank, the law and economics of market power is a confusing mess. See Louis Kaplow, Why (Ever) Define Markets?, 124 Harv. L. Rev. 437, 440 (2010) ("Defects [of the market definition/market share paradigm] have been identified by courts, enforcement agencies, and both legal and economic commentators.

[1] The market power summary-judgment record includes Plaintiffs' Statement of Disputed Facts, which does not, contrary to Defendants' suggestion, deserve to be stricken under Local Rule 56. See D.R.I. LR Cv 56. The Court DENIES Defendants' motion, ECF No. 610.

No one believes that the market definition process is flawless or that market power inferences drawn from market shares are uniformly reliable, or even nearly so."). And when applied in the pharmaceutical context, it really shows its warts. But this much we know: Market power and monopoly power can be established by the same kind of evidence, either direct or indirect. Direct evidence of market power includes proof such as supracompetitive prices or reduced output. Ohio v. Am. Express Co., 138 S.Ct. 2274, 2283-85 (2018) (Section 1) ("Direct evidence of anticompetitive effects [is] proof of . . . reduced output, increased prices, or decreased quality in the relevant market." (citation omitted)).[2] Proof of market power can also come indirectly by defining a market

[2] In Coastal Fuels of Puerto Rico v. Caribbean Petroleum Corp., 79 F.3d 182, 196-99 (1st Cir. 1996) (Section 2), the First Circuit noted direct evidence included "actual supracompetitive prices and restricted output." Coastal Fuels, 79 F.3d at 196 (emphasis added). Economic theory holds that an increase in price restricts output, however, because of the consequent demand decrease. See, e.g., Sumanth Addanki Dep. 202:11-18, ECF No. 603-14. This is known in economics as the law of demand, id., and arguably obviates the need for Plaintiffs separately to prove output restriction where it has shown supracompetitive prices. The court in In re Solodyn (Minocycline Hydrochloride) Antitrust Litigation recently held, relying on Coastal Fuels, that pharmaceutical-purchaser plaintiffs needed evidence of both supracompetitive prices and restricted output to prove market power. No. 14-md-02503, 2018 WL 563144, at *12 (D. Mass. Jan. 25, 2018). In doing so, the court did not consider the economic principle that, all else equal, an increase in price restricts output due to the consequent demand decrease. The Solodyn court also was without the benefit of the Supreme Court's recent opinion in American Express. See Am. Express Co., 138 S.Ct. at 2284, quoted above.

and determining the defendant's share of that market. Coastal Fuels of P.R. v. Caribbean Petroleum Corp., 79 F.3d 182, 197 (1st Cir. 1996); Flovac, 817 F.3d at 853-54.

Case law suggests that when direct evidence is dispositive, indirect evidence is unnecessary. F.T.C. v. Ind. Fed'n of Dentists, 476 U.S. 447, 460-61 (1986); In re Nexium (Esomeprazole) Antitrust Litig., 968 F. Supp. 2d 367, 388 n.19 (D. Mass. 2013) ("Nexium I") ("Where direct evidence of market power is available . . . a plaintiff need not attempt to define the relevant market."). This is because "inquiries into market definition and market power . . . [are] but a surrogate for detrimental effects" on competition. Ind. Fed'n of Dentists, 476 U.S. at 460-61 (citation omitted); Coastal Fuels, 79 F.3d at 197 ("[F]inding the relevant market and its structure is not a goal in itself but a surrogate of market power[.]") (citation omitted); In re Aggrenox Antitrust Litig., 94 F. Supp. 3d 224, 246 (D. Conn. 2015) ("Aggrenox I") ("[W]hen direct evidence is available that a party profitably charges supracompetitive prices, the existence of market power can be established from that fact alone."). But where direct and indirect evidence are instructive, and neither dispositive, the factfinder should evaluate both.[3]

[3] On this, both sides agree that a factfinder should consider both direct and indirect evidence together, recognizing that it is impermissible for the Court to require separate presentations of direct and indirect evidence of market power. See Defs.' Market

In the specialized field of pharmaceutical antitrust reverse payment cases, the Supreme Court's seminal holding, F.T.C. v. Actavis, Inc., tells us that "where a reverse payment threatens to work unjustified anticompetitive harm the patentee likely possesses the power to bring that harm about in practice." Actavis, 570 U.S. 136, 157 (2013); see also In re Aggrenox Antitrust Litig. ("Aggrenox II"), 199 F. Supp. 3d 662, 666 (D. Conn. 2016) ("a large reverse payment is . . . a strong indicator of market power"); id. ("[a] large reverse payment is itself suggestive of market power"). And, to evaluate whether a reverse payment is an unreasonable restraint prohibited by Section I, it must be tested by the rule of reason. See Actavis, 570 U.S. at 156.

The rule of reason has been equated with "an inquiry into market power and market structure" intended to assess the actual effect of the restraint. Copperweld Corp. v. Indep. Tube Corp.,

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Power Responses 11, ECF No. 1251 ("Defendants believe it would be, to say the least, highly inappropriate to limit the jury to purported 'direct' evidence in an 'initial[]' phase, having the jury reach a verdict on such evidence, and only then potentially hear traditional (i.e., 'indirect') evidence regarding competition and monopoly power.") (emphasis added); Pls.' Answers to the Court's Questions for Further Market Power Briefing 9, ECF No. 1252 ("If the Court denies Plaintiffs' motion for summary judgment, it should submit the issue of market power to the jury to be decided at the conclusion of the first phase of the trial based on whatever evidence the parties choose to submit to the jury on that issue. Market power and market definition constitute a single issue that may be addressed using direct or indirect evidence.").

467 U.S. 752, 768 (1984). It requires the factfinder to "weigh[] all of the circumstances of a case in deciding whether a restrictive practice should be prohibited as imposing an unreasonable restraint on competition." Leegin Creative Leather Prods. v. PSKS, Inc., 551 U.S. 884, 885 (2007) (quoting Cont'l T. V., Inc. v. GTE Sylvania Inc., 433 U.S. 36, 49 (1977)). These circumstances include "specific information about the relevant business"; "the restraint's history, nature, and effect"; and "[w]hether the businesses involved have market power." Id. at 885-86. To that end, "[i]n its design and function the rule distinguishes between restraints with anticompetitive effect that are harmful to the consumer and restraints stimulating competition that are in the consumer's best interest." Id. at 886.

The question, in the end, is whether Warner Chilcott was in a position with Loestrin to inflict anticompetitive harm, that is, whether it had sufficient "market power". Having the benefit of trenchant briefing and argument, and concluding that genuine issues of material fact are an insurmountable hurdle to the answer, the Court denies the pending cross-motions, ECF Nos. 496, 569, and will submit this matter to the jury.

First, the definition of the market at issue is a question of fact. See In re Impax Labs., Inc., No. 9373, 2019 WL 1552939, at *25 (F.T.C. Mar. 28, 2019) ("To establish market power, a plaintiff typically first defines the relevant antitrust market"); see also

Flovac, 817 F.3d at 853 ("The definition of the relevant market is ordinarily a question of fact[.]"); Loestrin II, 261 F. Supp. 3d at 326 ("Defendants concede, as they must, that courts generally treat this fact-intensive issue as one to be decided on a motion for summary judgment (if no genuine issue of material fact exists) or at trial."). Plaintiffs and Defendants disagree about the products that make up the market capable of constraining Warner Chilcott's profit margins and price to a competitive level. Defendants are adamant that the oral contraceptive market is an unusually crowded one with over one hundred available hormonal contraceptives: Defendants say the consequent competition could not possibly allow a single brand to gain market power of any concern, and adding one more competitor — generic or otherwise — would be just a drop in the bucket. Plaintiffs predictably oppose this characterization, urging the Court instead to rule as a matter of law that this is a single-product market. And Plaintiffs have some support for their position because Actavis recognizes that "a branded drug and its generic equivalents could — and, in the reverse payment context, often would — together constitute an antitrust-relevant market." Impax, 2019 WL 1552939, at *25 (citing Actavis, 570 U.S. at 157).

The practical reality is that the pharmaceutical market is rife with idiosyncrasies. And while several courts in comparable cases have held that the relevant market was a single-product

market, market power looks different from one case to the next. See Am. Express, 138 S.Ct. at 2285 ("[C]ourts should 'combin[e]' different products or services into 'a single market' when 'that combination reflects commercial realities.'" (quoting United States v. Grinnell Corp., 384 U.S. 563, 572 (1966)); compare Mylan Pharm. Inc. v. Warner Chilcott Pub. Ltd. Co., 838 F.3d 421, 436 (3d Cir. 2016) ("Doryx") (affirming district court decision that relevant market was broad, consisting of all oral tetracyclines prescribed to treat acne) with Nexium I, 968 F. Supp. 2d at 389 (holding the branded drug and its generic to be a plausible relevant market). Facing the record evidence (documentary, testimonial, and expert) before the Court which, among other things, includes wildly variant estimates of price cost margins (depending on which costs are included, the time frame of the comparisons, and the relevant comparators); differing descriptions of the relevant market – from hundreds of hormonal contraceptives to a single molecule based market; and the highly disputed nature and value of the claimed reverse payments, which may be strong evidence of market power (along with, potentially, the other anticompetitive conduct alleged), the Court is left with the firm view that granting summary judgment for either party would encroach on the function of the jury.[4]

[4] Defendants' plaint that brand manufacturers generally have higher fixed costs than generics, given the resources it takes to

In reaching this conclusion, and with trial just around the bend, the Court rules on several market power Daubert motions as follows. As to physician prescribing practices, Defendants' Motion to Exclude Certain Opinions and Testimony of Dr. Richard J. Derman, ECF No. 781, and Defendants' Motion to Exclude Certain Opinions and Testimony of Michael Thomas, M.D., ECF No. 640, are GRANTED IN PART AND DENIED IN PART. First, Dr. Derman may not testify as to what all physicians do or consider in making prescribing decisions. He may, however, testify to his own prescribing decision-making process and knowledge, as well as that of his colleagues or other doctors with whom he has personal experience. See Bartlett v. Mut. Pharm. Co., Inc., 742 F. Supp. 2d 182, 195 (D.N.H. 2010) ("Indeed, most courts have prohibited

innovate and submit a successful NDA, is a red herring. See Kaplow, supra, at 499-500 (explaining that, fixed costs notwithstanding, "clarity in analysis is best served by maintaining the traditional distinction between the definition and measurement of market power, on one hand, and the determinants of liability, on the other"). High brand margins indeed may be necessary to recoup costs sunk into research and development, but the antitrust laws are not concerned with why brands need these margins, but instead how they got and, more to the point, maintained them. See 4A Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law: An Analysis of Antitrust Principles and Their Application ¶ 402b3 (4th ed. 2019) ("[T]he appropriate scope of protection to be given to innovation is primarily the concern of the intellectual property laws."). For these reasons, and as foreshadowed by earlier colloquies with counsel, Defendants may not introduce evidence of sunk costs to disprove market power at trial.

experts from testifying 'about what all doctors generally consider in making prescription decisions' or about 'what doctors generally think' . . . ." (citations omitted)). For example, Dr. Derman would be free to provide a counter-opinion to that of Dr. Darney that speaks to how he "and other clinicians with whom [he] worked and interacted during [his] career" prescribe oral contraceptives. See Darney Report ¶ 28, ECF No. 654-2. He may also provide an opinion that he and Defendants' experts agree as to certain topics, and any disagreement on that score may be addressed by Defendants on cross-examination. Second, Dr. Derman may provide his opinion that, for some patients, "there may be one [combination oral contraceptive] which is more appropriate than any other[.]" See Derman Report ¶ 17, ECF No. 782-2. Third, Dr. Derman may not – without more - speculate that other experts' opinions may be due to reimbursement constraints unique to California. See id. ¶ 20.

With respect to Dr. Thomas, and consistent with the discussion between counsel and the Court at the September 12, 2019 Daubert hearing, Plaintiffs agree that Dr. Thomas's testimony on prescribing practices, behavior, and knowledge will be limited to his own experience, and that Dr. Thomas will not be permitted to testify as to what all physicians do or if it is common for physicians to do something. Dr. Thomas may testify from his own experience. The same applies regarding any opinions he may offer relating to the impact of cost on patient behavior. Dr. Thomas

may similarly opine on his experience regarding the interchangeability of contraceptives but may not more generally opine on how all doctors view this issue.

Moreover, after careful consideration of the pertinent briefing and underlying expert reports and rebuttal materials, the Court DENIES the Daubert motions filed to preclude the opinions and testimony of Defendants' and Plaintiffs' economic experts. Accordingly, the Court DENIES Defendants' Motions to Exclude the Opinions and Testimony of Plaintiffs' Expert Dr. Christopher F. Baum and Certain Opinions of Dr. Meredith Rosenthal, ECF No. 646, and Plaintiffs' Motion to Exclude the Expert Testimony of Dr. Sumanth Addanki, ECF No. 711. See In re Solodyn (Minocycline Hydrochloride) Antitrust Litig., No. 14-md-2503, 2018 WL 563144, at *7, 9, 10 n.17 (D. Mass. Jan. 25, 2018) ("Solodyn I") (rejecting Daubert challenges to Drs. Baum's, Rosenthal's, and Addanki's opinions and testimony).

B. Summary Judgment

Having determined that the jury will decide the issue of market power, the Court turns to Defendants' motion for summary judgment on the merits and the accompanying Daubert motions.[5]

[5] In connection with the present motion for summary judgment, Plaintiffs and Defendants have filed the following Daubert motions (in addition to those already decided): Defendants' Motion to Exclude Certain Opinions and Testimony of Edward Lentz, John Doll, and Nicholas Jewell, ECF No. 890; Defendants' Motion to Exclude Opinions and Testimony of Plaintiffs' Expert Dr. Thomas McGuire,

1. Plaintiffs' But-For World

Defendants' first line of attack is a whopper. They assert that Plaintiffs cannot establish a viable but-for world for their Walker Process claim, because if the patent was procured by fraud and therefore invalid, there would have been no patented product and no one would have been injured in the but-for world. No patent, no product; no product, no purchases; no purchases, no damages, Defendants say. Voila! The problem is this argument has no basis in law and would nullify antitrust liability in any case involving Walker Process fraud alongside another antitrust violation. It is untenable[6] and ignores the reality of the anticompetitive conduct as alleged.

ECF No. 882; Defendants' Motion to Exclude the Opinions and Testimony of John R. Tupman, ECF No. 892; Defendants' Motion to Exclude Certain Opinions and Testimony of Michael Thomas, M.D., on Chewability and Patent Issues, ECF No. 886; Plaintiffs' Motion to Exclude Opinions and Testimony of Drs. Christine S. Meyer, Mark S. Robbins, and Melissa S. Schilling Regarding Lack of Anticompetitive Effect from Product Hop, ECF No. 875; Plaintiffs' Motion to Exclude the Expert Testimony of Dr. Louis Berneman, Philip Green, and Dr. Christine Meyer Regarding "Fair Value", ECF No. 902; Plaintiffs' Motion to Exclude Opinions and Testimony of Drs. Christine S. Meyer and Mark S. Robbins Regarding Procompetitive Justifications of Reverse Payments, ECF No. 874; Plaintiffs' Motion to Exclude Portions of Testimony of Defendants' Expert Dr. Pierre-Yves Cremieux, ECF No. 906; and Plaintiffs' Motion to Exclude in Part the Expert Opinions of Christine Meyer, Ph.D and Philip Green That Authorized Generics Were Facing Legal Uncertainty, ECF No. 901.

[6] Defendants' argument turns a blind eye to well-settled law that antitrust injury occurs when a purchase is made at an inflated price. Hanover Shoe, Inc. v. United Shoe Mach. Corp., 392 U.S. 481, 489 (1968); see also In re Loestrin 24 Fe Antitrust Litig.,

2. Walker Process Fraud

That settled, Defendants next claim broadly that Plaintiffs fail to identify a triable issue with respect to Walker Process fraud, a claim that centers on whether the ´394 patent was procured by fraud. Under a Walker Process fraud theory, antitrust liability is imposed on those who enforce a patent they know to be procured by knowing and willful fraud on the U.S. Patent and Trademark Office ("PTO").[7] See Walker Process Equip., Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172, 179 (1965) (Harlan, J., concurring). For the Court to enter judgment for Defendants on Plaintiffs' Walker Process fraud claim now, Defendants must show there is no genuine dispute as to any material fact, even when all reasonable inferences are drawn in Plaintiffs' favor. See Fed. R. Civ. P. 56; see also Exergen Corp. v. Kaz USA, Inc., 120 F. Supp. 3d 1, 6 (D. Mass. 2015).

In Walker Process fraud, "it is the enforcement of a patent procured by fraud that may give rise to a Sherman Act claim; mere

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No. 13-2472-WES-PAS, 2019 WL 3214257, at *5 n.10 (D.R.I. July 2, 2019) (reasoning that purchasers are injured at the point they incur the overcharge); In re Skelaxin (Metaxalone) Antitrust Litig., No. 1:12–md–2343, 2014 WL 2002887, at *5 (E.D. Tenn. May 15, 2014) ("Hanover Shoe and Illinois Brick make clear that courts and juries will not be forced down the rabbit hole of hypothetical issues antitrust violators may raise to minimize their liability.").

[7] Defendants' arguments on this claim partially mimic those argued at the motion-to-dismiss phase, now with the benefit of a more developed record.

procurement without more does not 'affect the welfare of the consumer and cannot in itself violate the antitrust laws.'" Loestrin II, 261 F. Supp. 3d at 339 (quoting FMC Corp. v. Manitowoc Co., 835 F.2d 1411, 1418 & n.16 (Fed. Cir. 1987)). Walker Process fraud is only actionable against those associated with the filing and prosecution of a patent application who owe a duty of candor and good faith to the PTO. See 37 C.F.R. § 1.56(c); see also Avid Identification Sys., Inc. v. Crystal Imp. Corp., 603 F.3d 967, 973 (Fed. Cir. 2010) (analyzing inequitable conduct). This includes (1) "[e]ach inventor named in the application"; (2) "[e]ach attorney or agent who prepares or prosecutes the application"; and (3) "[e]very other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, the applicant, an assignee, or anyone to whom there is an obligation to assign the application." Id.

To succeed, then, "the plaintiff must show that the defendant procured the relevant patent by knowing and willful fraud on the PTO or (in the case of an assignee) that the defendant maintained and enforced the patent with knowledge of the fraudulent manner in which it was obtained." Ritz Camera & Image, LLC v. SanDisk Corp., 700 F.3d 503, 506 (Fed. Cir. 2012) (recognizing that "invalidity of the patent [is] not sufficient; a showing of intentional fraud in its procurement [is] required."). In addition, Plaintiffs must also show "all the other elements necessary to establish a Sherman

Act monopolization claim." TransWeb, LLC v. 3M Innovative Properties Co., 812 F.3d 1295, 1306 (Fed. Cir. 2016). Thus, here, apart from monopoly power, there are two required showings: first, that the patent was procured by knowing and willful fraud; and second, knowing of the fraud, Warner Chilcott enforced it anyway. See id.

Fraudulent procurement requires evidence of (1) a misrepresentation or omission made to the PTO (2) material to the patent's issuance, (3) made with intent to deceive the PTO. Nobelpharma AB v. Implant Innovations, Inc., 141 F.3d 1059, 1070-71 (Fed. Cir. 1998). "But-for" materiality is required, meaning that "the patent would not have issued but for the misrepresentation or omission."[8] Id. at 1071; see also Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1291 (Fed. Cir. 2011). Intent to deceive must be "the single most reasonable inference able to be drawn from the evidence."[9] Therasense, 649

[8] "But-for" materiality is not required in cases of egregious misconduct, such as filing an unmistakably false affidavit. See Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1292 (Fed. Cir. 2011). Plaintiffs do not meaningfully argue that this standard applies here.

[9] While this standard applies to inequitable conduct claims, cases discussing intent for Walker Process fraud do not explicitly reference the "single most reasonable inference" standard. See Shuffle Tech Int'l LLC v. Sci. Games Corp., No. 15 C 3702, 2017 WL 3838096, at *11 (N.D. Ill. Sept. 1, 2017) ("Although the standards appear to be largely the same, cases discussing Walker Process fraud omit the requirement that fraudulent intent must be the 'single most reasonable inference'

F.3d at 1290 (quoting Star Scientific, Inc. v. R.J. Reynolds Tobacco Co., 537 F.3d 1357, 1366 (Fed. Cir. 2008)).

To this end, Plaintiffs carry the "burden to show 'no less than clear, convincing proof of intentional fraud involving affirmative dishonesty.'" Tyco Healthcare Grp. LP v. Mut. Pharm. Co., Inc., 762 F.3d 1338, 1350 (Fed. Cir. 2014) (quoting C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1364 (Fed. Cir. 1998)). "Because direct evidence of deceptive intent is rare, a district court may infer intent from indirect and circumstantial evidence." Therasense, 649 F.3d at 1290. That said, "the evidence 'must be sufficient to require a finding of deceitful intent in the light of all the circumstances.'" Id. (quoting Kingsdown Med. Consultants, Ltd. v. Hollister Inc., 863 F.2d 867, 873 (Fed. Cir. 1988) (emphasis in original)). Thus, "when there are multiple reasonable inferences that may be drawn, intent to deceive cannot be found." Id. at 1290–91. The question here is whether Plaintiffs have proffered clear and convincing evidence that could support a jury determination of an intent to deceive by the

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that can be drawn from the evidence."). But see Inline Packaging, LLC v. Graphic Packaging Int'l, LLC, 351 F. Supp. 3d 1187, 1203 (D. Minn. 2018) (applying "single most reasonable inference" standard in analyzing Walker Process fraud). That said, Plaintiffs seem to accept the fact that the "single most reasonable inference" is the standard. Pls.' Opp'n to Defs.' Mot. for Summ. J. 9-10, ECF No. 978 ("The only inference that can be drawn from the evidence is that [Dr.] Hodgen intended to deceive the PTO . . . .") (emphasis added).

applicant, and that this is the single most reasonable inference the jury could draw from the evidence. Id. at 1290.

Defendants argue Plaintiffs cannot meet this high evidentiary bar for any of the three factual bases that form their Walker Process fraud claim. Those bases are: (1) the so-called "Molloy Article"; (2) the 30-Woman Study ("the Study"); and (3) the Loestrin 1/20 Fe ("Loestrin 1/20") Reference. To address each of these in detail, and to understand just what Plaintiffs would offer to the jury to meet their burden, it is necessary to first resolve Defendants' motion to exclude certain opinions and testimony from Plaintiffs' patent experts: Mr. Lentz, Mr. Doll, and Dr. Jewell.

a. Defendants' Motion to Exclude Certain Opinions and Testimony of Edward Lentz, John Doll, and Nicholas Jewell, ECF No. 890

Defendants move to exclude these expert opinions on multiple grounds. First, Defendants argue that Mr. Lentz is not qualified to opine that Watson had a 90% likelihood of success in Warner Chilcott's litigation against it. They emphasize that Mr. Lentz has never worked as a patent litigator, and instead served only as general counsel of GlaxoSmithKline. But other courts have permitted similar expert opinions on likelihood of success. See, e.g., Namenda I, 331 F. Supp. 3d at 188. While Defendants distinguish these cases, the Court finds them persuasive.

Defendants may address any perceived shortcomings of Mr. Lentz's qualifications and his opinion on cross-examination.[10]

Next, Defendants argue that Mr. Lentz improperly opines about materiality, the significance of prior art references, and technical patent issues; opinions that may only come from a person of ordinary skill in the art ("POSA"), which Mr. Lentz is not. Defendants make the same arguments related to Mr. Doll, alleging he discusses similar technical matters, as well as the materiality of references.

It is true that only a POSA may opine on these technical patent law issues. See Sundance, Inc. v. DeMonte Fabricating Ltd., 550 F.3d 1356, 1362 (Fed. Cir. 2008). But these experts clearly do not do so. Mr. Lentz's opinions are "directed to how a patent attorney in the field would have evaluated the prosecution of the ´394 patent and what advice and opinions a patent attorney would have given to his or her client regarding that prosecution and the related litigation." Pls.' Opp'n to Defs.' Mot. To Exclude Lentz, Doll, and Jewell 7, ECF No. 1024. And Mr. Doll offers his conclusions in the context of evaluating the ´394 patent's prosecution history. Each expert relies on the references

[10] Defendants also question Mr. Lentz's methodology. The Court is satisfied that Mr. Lentz connects his experience to his opinions. Nor does the Court find persuasive Defendants' argument that Mr. Lentz's opinion should be excluded for considering, or failing to consider, certain evidence. Defendants may address these concerns, if appropriate, on cross-examination.

themselves (or another expert) for his opinions. Thus, so long as Mr. Lentz and Mr. Doll only evaluate these issues from their respective perspectives, and do not offer legal conclusions on technical patent issues, their opinions are allowed.[11] See Namenda I, 331 F. Supp. 3d at 187 (recognizing that it is the perspective from which the expert opines that is significant); see also Solodyn I, 2018 WL 563144, at *17-18 (finding Mr. Doll qualified to offer an opinion as to what a reasonable patent officer would find material in a patent application and relevant PTO policies and procedures, but not for legal conclusions).

Third, Defendants argue Dr. Jewell impermissibly offers opinions outside his statistical expertise in opining on the clinical significance and relevance of the 30-Woman Study, the primate study, and the Phase III Clinical Trial. Dr. Jewell is qualified as a biostatistician, sure – but without expertise as a clinician, Defendants say he cannot testify about whether the results of any study would be relevant or significant. The Court is satisfied that he is qualified to opine on the statistical merits of the studies (but not their clinical significance).

[11] Defendants seek to exclude these experts' opinions as unreliable because they are self-contradictory and directly contradict relevant PTO regulations. If Mr. Lentz or Mr. Doll's opinions directly contradict PTO regulations, or otherwise misstate them, they will be excluded. But if these opinions set forth a reasonable interpretation of the regulations, Defendants' motion is DENIED.

Defendants next posit that Dr. Jewell's analysis of breakthrough bleeding from the 30-Woman Study data should be excluded as unreliable and irrelevant where Dr. Jewell is not qualified to manipulate and analyze data about bleeding days from a human study using definitions from a primate study.[12] The Court is again satisfied that Dr. Jewell is qualified to offer these opinions; Defendants' concerns are best addressed on cross-examination.

Lastly, Defendants argue that Dr. Jewell, Mr. Lentz, and Mr. Doll improperly opine on intent and/or state of mind. At oral argument, Plaintiffs assured the Court their experts will not express such opinions, and instead will only reference documents from which a jury could find facts that may support a jury determination on intent to deceive. If any expert attempts to opine on intent and state of mind, legal conclusions, or speculates about the patent examiner's state of the mind, those opinions will be excluded and appropriate corrective instructions will be given to the jury.[13] See Solodyn I, 2018 WL 563144, at *18 n.25. Further,

[12] Defendants ask the Court to exclude Dr. Jewell's opinion as irrelevant to Plaintiffs' fraud theories because no evidence suggests that this re-analysis of data was performed during the patent prosecution and intentionally kept from the PTO. This is not a valid reason to exclude these opinions.

[13] Defendants submit that the Court should exclude "any purported identification of facts in support of opinions[.]" Sept. 12, 2019 Hr'g Tr. 35. Plaintiffs suggest that Mr. Lentz should be allowed to identify facts from which an inference of intent can be

neither side will be permitted to offer cumulative opinions.[14] For these reasons, Defendants' Motion to Exclude Certain Opinions and Testimony of Edward Lentz, John Doll, and Nicholas Jewell, ECF No. 890, is GRANTED IN PART AND DENIED IN PART. The motion is DENIED except to the extent, as discussed above, that these experts opine on intent and/or state of mind, legal conclusions, offer cumulative opinions, or speculate about the patent examiner's state of mind.

b. Plaintiffs' Evidence of Walker Process Fraud[15]

To set the stage to address the merits of Defendants' Walker Process fraud arguments, it is helpful to recap the cast of characters implicated and their respective alleged misdeeds. Dr.

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drawn, but Defendants argue that all Mr. Lentz relies on are privilege log entries, handwritten notes, and documents outside the prosecution history. The Court will not exclude Mr. Lentz's opinion testimony on this basis.

[14] And, considering the applicable time restrictions, the Court is confident that neither side will be incentivized to do so.

[15] Overarchingly, Defendants consider telling the decision of some of the generic manufacturers to not raise an inequitable conduct defense in the underlying patent infringement suits, claiming it undercuts Plaintiffs' present Walker Process fraud claim. Two of the generic firms (Lupin and Mylan) did not bring inequitable conduct claims post-Star Scientific and post-Therasense, respectively; Watson did assert an inequitable conduct claim. While these generic challengers' decision not to assert this defense is perhaps relevant, it is not dispositive. As with any claim, a party might refrain from asserting a defense for any number of reasons. See generally Gideon Mark & T. Leigh Anenson, Inequitable Conduct and Walker Process Claims After Therasense and the America Invents Act, 16 U. Pa. J. Bus. L. 361, 370 (2014) (recognizing that "the defense has an army of critics").

Gary Hodgen, a researcher at the Jones Institute for Reproductive Medicine ("Jones Institute") at the Eastern Virginia Medical School ("EVMS"), is the named inventor of the ´394 patent, which he assigned to EVMS and EVMS eventually assigned to Warner Lambert. PSOF ¶¶ 10, 11, 39. Edward Meilman — Dr. Hodgen's experienced patent attorney — aided Dr. Hodgen with the patent prosecution that led to the ´394 patent. PSOF ¶¶ 12, 14. Roger Boissonneault, Anthony Bruno, and Carl Reichel worked for Warner Lambert (or one of its subsidiaries) during the patent prosecution and became executives at Warner Chilcott. PSOF ¶ 12. Francis ("Frank") Tinney similarly worked for Warner Lambert at the relevant time as a patent attorney. Plaintiffs' Additional Statement of Material Undisputed Facts ("ASOF") ¶ 226, ECF No. 980.

Warner Chilcott did not own or license the ´394 patent when it was prosecuted; it came to own the patent nine years after it issued.[16] ASOF ¶ 237. Plaintiffs bridge this seemingly significant time gap by claiming that these Warner Chilcott executives — then employed by Warner Lambert — were substantively involved in the patent's prosecution and Warner Chilcott's later acquisition of it, and carried their knowledge of fraudulent conduct with them to

[16] The parties dispute when the patent assignment from Dr. Hodgen to Warner Lambert occurred; Plaintiffs say in 1994, and Defendants say in 1996. PSOF ¶ 39. The Court makes all reasonable inferences in Plaintiffs' favor.

Warner Chilcott, which then enforced the patent in spite of that knowledge of fraud.

Attacking the foundation of Plaintiffs' claims, Defendants say they failed to plead the fraud allegations with particularity, as required by Rule 9(b), against Carl Reichel, Anthony Bruno, and Frank Tinney. See Fed. R. Civ. P. 9(b). "The core purposes of Rule 9(b) are 'to place the defendants on notice and enable them to prepare meaningful responses,' 'to preclude the use of a groundless fraud claim as pretext for discovering a wrong,' and 'to safeguard defendants from frivolous charges [that] might damage their reputation.'" Dumont v. Reily Foods Co., 934 F.3d 35, 39 (1st Cir. 2019) (quoting New England Data Servs., Inc. v. Becher, 829 F.2d 286, 289 (1st Cir. 1987)). Defendants do not argue that they required any further particularity to respond to the complaints. Rather, they claim that Plaintiffs are impermissibly arguing new fraud theories at the summary judgment stage.

The Court is satisfied that Plaintiffs adequately put Warner Chilcott on notice of these claims. For example, in their Third Amended Consolidated Complaint, the DPPs allege that "Warner Chilcott, through its executives, knew the ´394 patent is [sic] invalid and/or unenforceable[.]" Direct Purchaser Class Pls.' Third Am. Consolidated Class Action Compl. and Jury Demand ("DPP Compl.") 38, ECF No. 380 (emphasis added). That pleading refers

to Mr. Boissonneault specifically and Warner Chilcott generally. See, e.g., id. ¶¶ 143, 144, 147, 152, 153. The EPPs' Second Amended Consolidated Complaint likewise refers to Dr. "Hodgen, counsel, and others substantially involved in its prosecution" collectively as the "applicants", alleging these people knew about the fraudulent misrepresentations. EPPs' Second Am. Consolidated Class Action Compl. ("EPP Compl.") ¶¶ 144, 147, ECF No. 165. And like the DPPs, the EPPs' Complaint calls out Mr. Boissonneault specifically and Warner Chilcott generally. Id. ¶¶ 150, 155, 156, 162, 168. The Retailers' respective Amended Complaints proceed in similar fashion, referring to Dr. Hodgen and Mr. Boissonneault, together with Warner Chilcott generally. CVS First Am. Compl. ("CVS Compl.") ¶¶ 75, 77, ECF No. 177-1; Walgreen First Am. Compl. ("Walgreen Compl.") ¶¶ 76, 78, ECF No. 176-1. The Retailers also refer to "senior Warner Chilcott executives – including [Mr.] Boissonneault" who "had been executives at Warner [] Lambert when Warner [] Lambert acquired and prosecuted the application that resulted in the ´394 patent[.]" CVS Compl. ¶ 77; Walgreen Compl. ¶ 80.

Germane here is: "[w]hat constitutes sufficient particularity necessarily depends upon the nature of the case and should always be determined in . . . light of the purpose of the rule to give fair notice to the adverse party and to enable him to prepare his responsive pleading." Alex & Ani, LLC v. Elite Level Consulting,

LLC, 31 F. Supp. 3d 365, 371 (D.R.I. 2014) (quoting Women's Dev. Corp. v. City of Central Falls, 764 A.2d 151, 161 (R.I. 2001)). "The circumstances to be stated with particularity under Rule 9(b) generally consist of 'the who, what, where, and when of the allegedly [misleading] representation.'" Kaufman v. CVS Caremark Corp., 836 F.3d 88, 91 (1st Cir. 2016) (quoting Alt. Sys. Concepts, Inc. v. Synopsys, Inc., 374 F.3d 23, 29 (1st Cir. 2004)). In these pleadings (and at this point in the case), it is clear Warner Chilcott is the "who", and the alleged fraud was perpetrated through Warner Chilcott's senior executives. See id. Warner Chilcott therefore had fair notice of these allegations.

i. Molloy Article

Turning to the substance of Defendants' challenges, the Molloy Article is the logical starting point. The EPPs and the Retailers (but not the DPPs) allege that Dr. Hodgen, himself or through his attorney, intentionally concealed the so-called "Molloy Article". Loestrin II, 261 F. Supp. 3d at 344 (citing B.G. Molloy et al., "Missed Pill" conception: fact or fiction?, 290 Brit. Med. J. 1474, 1475 (1985)). This Article contains the following statement: "To reduce the risk of missed pill conception a 28 day pack containing 23 pills and 5 blanks could be substituted for the current 21 day pack. This would still permit a withdrawal bleed without the risk of significant follicular development." Id.

Defendants claim that Plaintiffs have marshaled no evidence that Dr. Hodgen or Mr. Meilman deliberately deceived the PTO. The Court agrees. To meet their burden, Plaintiffs must show evidence from which a rational juror could find by clear and convincing evidence that an intent to deceive is the single most reasonable inference. "A mere failure to cite a reference to the PTO will not suffice." Nobelpharma, 141 F.3d at 1071; see also Dippin' Dots, Inc. v. Mosey, 476 F.3d 1337, 1347 (Fed. Cir. 2007). Rather, "there must be evidence of intent separable from the simple fact of the omission." Dippin' Dots, 476 F.3d at 1347. This is because an omission "could happen for any number of nonfraudulent reasons — the applicant could have had a good [] faith belief that disclosure was not necessary, or simply have forgotten to make the required disclosure." Id.

Attempting to point to evidence of a transgression, Plaintiffs cite a December 31, 1990 letter Dr. Hodgen wrote to Beatrice Allis (of Warner Lambert), copying Mr. Boissonneault, after Warner Lambert asked Dr. Hodgen to comment on the Article. Plaintiffs also cite Dr. Hodgen's notations on an attached research protocol applying the Molloy Article's reasoning. PSOF ¶ 20. The letter does not attach the Molloy Article. Id. The parties dispute various aspects of this correspondence, including whether Dr. Hodgen agreed with the Article's relevant claim and whether the Article taught taking Loestrin 1/20. Id. Plaintiffs cobble

together evidence they contend shows that Dr. Hodgen did in fact agree with the Article's relevant suggestion.

But no matter. Even with all reasonable inferences drawn in Plaintiffs' favor, where there are two or more equally plausible inferences – forgetting and intentionally omitting – Plaintiffs must do more than say "yeah, right". And here, they have simply failed to identify any evidence – let alone clear and convincing evidence – beyond the omission itself to show a purposeful intent to deceive. See C.R. Bard, Inc., 157 F.3d at 1365 ("Deceptive intent is not inferred simply because information was in existence that was not presented to the examiner[.]"). Even assuming Plaintiffs can show but-for materiality, Plaintiffs' evidence related to intent to deceive falls short and so this issue cannot sustain Plaintiffs' Walker Process fraud claim. The Molloy Article may not be utilized by Plaintiffs.

ii. 30-Woman Study

Plaintiffs' reliance on the 30-Woman Study fares better. Plaintiffs claim Dr. Hodgen's failure to disclose this Study amounted to a material omission. The 30-Woman Study "was designed to determine whether Loestrin 1/20 would suppress ovarian activity more efficiently when given for a 25 day regimen as opposed to the normal 21 day cycle of the pill[.]" Defendants' Statement of Undisputed Facts ("DSOF") ¶ 28, ECF No. 860. Its objective "was to establish that a shorter pill free interval could increase the

efficacy of low dose contraceptives while providing a more regular and agreeable bleeding pattern." Id.

The standard is the same. Plaintiffs cry foul because Dr. Hodgen referenced an "embargo[]" of the Study's data and agreed to delay publishing the results. PSOF ¶ 34. And while Defendants can point to evidence that shows Dr. Hodgen thought the Study was "predicated from the preclinical primate data" and was thus consistent with the primate study (which was disclosed), this merely reflects a dispute of fact. DSOF ¶¶ 27, 34. The real question is whether the jury could find that intent to deceive is the single most reasonable inference. Therasense, 649 F.3d at 1290. Defendants say not, particularly where Mr. Lentz has admitted that the claim preamble may be interpreted in two ways; these differing interpretations, they say, disprove that reduced incidence of breakthrough bleeding is a claim limitation (if this is not a claim limitation, then omission of the Study would be of no moment).

This is a close call. Nevertheless, the Court determines that from these facts, a reasonable jury could find by clear and convincing evidence that intent to deceive is the single most reasonable inference from Dr. Hodgen's failure to disclose the 30-Woman Study. See Nobelpharma, 141 F.3d at 1071.

The analysis does not end there, however; Plaintiffs must also show that Warner Chilcott knew about this fraud. To do so

they claim that Warner Lambert employees, who eventually became Warner Chilcott executives, were substantively involved in the patent prosecution.[17,18] They cite evidence that Mr. Boissonneault, Mr. Reichel, and Mr. Bruno knew of these misrepresentations. They argue that Mr. Boissonneault conceived of the invention with Dr. Hodgen, and was substantively involved in the application, as well as Warner Lambert/Parke-Davis's acquisition of the patent from the Jones Institute. PSOF ¶¶ 12, 39. Defendants contend that Mr. Boissonneault and Dr. Hodgen discussed a different hormonal contraceptive and that Mr. Boissonneault was not involved in the ´394 patent's conception. Defs.' Resp. to Pls.' Additional Statement of Undisputed Facts ("DASOF") ¶ 223, ECF No. 1054-1. Plaintiffs emphasize that Mr. Boissonneault was alerted when the 30-Woman Study was complete, including that it evidenced no

[17] Through a recently filed motion in limine, see ECF No. 1300, Plaintiffs seek to prevent Warner Chilcott from arguing that Warner Chilcott executives were not involved in the ´394 patent prosecution or assignment because, Plaintiffs say, Defendants obscured relevant and discoverable evidence. The Court referred this motion to Magistrate Judge Sullivan, and Judge Sullivan denied it.

[18] On this point (and others) Defendants challenge Plaintiffs' reliance on a privilege log, seeking to prevent Plaintiffs' use of the log as evidence. The Court referred the related motion in limine to Magistrate Judge Sullivan, and Judge Sullivan granted it in part and denied it in part. Accordingly, to the extent Plaintiffs rely on the privilege log as evidence to oppose this motion, the Court does not consider it, and Plaintiffs may not present such evidence to the jury except as directed in that order.

statistically significant difference in cycle control. PSOF ¶ 12. They say Warner Lambert knew internally that the 30-Woman Study revealed "no statistically significant difference in cycle control[.]" Id. ¶¶ 12, 33. Plaintiffs further claim that certain of these executives received drafts of the patent application and that Mr. Bruno directed EVMS to continue preparing it. Id. ¶ 39. These are all issues of fact for the jury. The Court is satisfied that Plaintiffs have submitted enough evidence from which a jury could find that Warner Chilcott enforced the patent with knowledge of this fraud.

Finally, Plaintiffs must submit evidence from which a reasonable juror could determine that the patent would not have issued but for this fraudulent omission. Nobelpharma, 141 F.3d at 1072. The parties' dispute as to materiality turns on the Study's purpose and whether that purpose is patently significant, and on this the parties disagree. PSOF ¶¶ 33, 34. Defendants claim the Study did not analyze breakthrough bleeding (rather, it analyzed bleeding generally), and thus it is duplicative of the primate study. DSOF ¶¶ 33, 34. Plaintiffs submit that it did analyze breakthrough bleeding and in fact proved inconsistent with the primate study. PSOF ¶ 33, 34.

To argue that breakthrough bleeding is patently significant, Plaintiffs cite arguments Mr. Meilman made in office actions to the PTO (as well as Dr. Lentz's expert opinions interpreting them)

to say that the patent examiner first rejected the patent because she doubted whether the invention actually reduced the incidence of breakthrough bleeding. Id. ¶¶ 37, 38. They say these doubts were eventually overcome by Mr. Meilman's breakthrough bleeding arguments. Id.

Defendants lean heavily on a favorable Markman claim-construction decision out of the U.S. District Court for the District of New Jersey. In an action like that brought by Warner Chilcott against Watson for patent infringement, Warner Chilcott sued one of Loestrin's generic manufacturers, Mylan Pharmaceuticals Inc. ("Mylan"), alleging infringement of the ´394 patent. Loestrin II, 261 F. Supp. 3d at 323. There, the court held that a reduced incidence of breakthrough bleeding is not a claim limitation of the ´394 patent. DSOF ¶¶ 64, 76. But that decision is not conclusive evidence here, and this is a clear fact dispute. PSOF ¶ 64. As such, a reasonable juror could conclude that the patent would not have issued had the PTO examiner known about this Study.

Separately, the EPPs and the Retailers argue that the 30-Woman Study constituted an "invalidating prior public use" of the invention, rendering the ´394 patent obvious and requiring the Study's disclosure to the PTO. Pls.' Opp'n to Defs.' Mot. for Summ. J. ("Pls.' Opp'n to Summ. J.") 6, ECF No. 978. They rely on evidence that the Study's subjects were given Loestrin 1/20 labels,

commercial blister packs of Loestrin 1/20, were recruited through public advertising, and had no obligation of secrecy. Id. at 7; PSOF ¶¶ 29.

The invalidating public use doctrine renders unpatentable an invention that was either in public use or on sale "more than one year prior to the date of the application for patent[.]" Invitrogen Corp. v. Biocrest Mfg., L.P., 424 F.3d 1374, 1379 (Fed. Cir. 2005) (citation omitted). A public use bar to patentability "arises where, before the critical date, the invention is in public use and ready for patenting." Id.; see also Weatherchem Corp. v. J.L. Clark, Inc., 163 F.3d 1326, 1332 (Fed. Cir. 1998). An invention is "ready for patenting" "in at least two ways: by proof of reduction to practice before the critical date; or by proof that prior to the critical date the inventor had prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention." Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 67–68 (1998).

Although close, the Court concludes that Plaintiffs have submitted enough evidence to allow a reasonable jury to find the invention was in public use and ready for patenting one year before the critical date of July 22, 1994. See id. Defendants argue the invention was not ready for patenting more than one year before the critical date because the Study was completed in September

1993, less than one year before July 22, 1994. DSOF ¶¶ 13, 29. But the Study began around four months earlier and nothing precludes the jury from finding that the invention was in public use and ready for patenting at that time. Id. ¶ 29; see Invitrogen, 424 F.3d at 1379. While Defendants cite evidence to support their claim that the Study was an experimental use,[19] which would negate both that the invention was ready for patenting and in public use, this is an issue of fact. Cf. Invitrogen, 424 F.3d at 1380 (holding that the invention was not a public use where the process was used in the inventor's own laboratories). Based on this evidence, a rational juror could conclude that the Study constituted an invalidating public use that should have been disclosed to the PTO. All aspects of this claim, then, may proceed to the jury.

iii. Loestrin 1/20 Reference

Plaintiffs' final basis for their Walker Process fraud claim – and probably their most persuasive – is the omission of Loestrin 1/20 as prior art. Plaintiffs argue Dr. Hodgen and Mr. Meilman fraudulently misrepresented the amount of estrogen in other commercially available oral contraceptives, and, had they been truthful that Loestrin 1/20 has less than 30 mcg ethinyl estradiol

[19] This evidence includes that the Study was four months long, had a small sample size, involved a controlled experiment, and that the protocol and final report were submitted to a board with strict confidentiality and record-keeping rules. See Barry v. Medtronic, Inc., 914 F.3d 1310, 1328 (Fed. Cir. 2019) (analyzing similar factors in evaluating experimental use).

("EE"), the patent would not have issued. Pertinently, the ´394 patent specification says the invention "provide[s] a new estrogen-progestin combination and regimen" with ultra-low doses that are less daily than those then-available. Pls.' Opp'n to Summ. J. 5. Meanwhile, Loestrin 1/20 is a combination oral contraceptive "consisting of 21 active pills containing 1 mg [norethindrone acetate] and 20 mcg EE, and 7 inactive pills containing ferrous fumarate." DSOF ¶ 5. It is undisputed that Loestrin 1/20 was the only combination oral contraceptive with less than 30 mcg of EE commercially available in the United States at that time. PSOF ¶ 23.

While Defendants claim Loestrin 1/20 was specifically disclosed in the patent application in Example 1, it is not, as Defendants say, "obvious" that this would sufficiently alert the patent examiner of its relevance as prior art. In fact, Plaintiffs say Dr. Hodgen steered the patent examiner away from Loestrin 1/20 by maintaining that the prior art did not include any commercially available oral contraceptives with less than 30 mcg EE. PSOF ¶ 22. Mr. Meilman told the patent examiner in an office action that "the claimed regimen leaves the patient with a total estrogen exposure per annum which is well below the total annual dose of estrogen in all other combination formulations commercially available in this country. Those all contain at least 30 mcg

EE[.]" DSOF ¶ 25. This, Plaintiffs say, is a deliberate falsehood.

"Burying" the most pertinent prior art can constitute deceptive conduct. See Semiconductor Energy Lab. Co. v. Samsung Elecs. Co., 204 F.3d 1368, 1376 (Fed. Cir. 2000), amended (Apr. 5, 2000) (finding no clear error in district court's finding that applicant willfully misrepresented reference to PTO where applicant did not provide complete and accurate translation); see also Advanced Ion Beam Tech., Inc. v. Varian Semiconductor Equip. Assocs., Inc., 721 F. Supp. 2d 62, 78 (D. Mass. 2010). Based on this evidence, a jury could conclude by clear and convincing evidence that intent to deceive is the single most reasonable inference where the patent examiner was arguably directed away from what is inarguably prior art.

Plaintiffs have also submitted sufficient evidence for a jury to conclude that Warner Chilcott knew of this fraud when it enforced the patent. For example, they cite evidence that Mr. Boissonneault, and the other pertinent executives, knew about Loestrin 1/20, including Mr. Boissonneault corresponding about an "extended regimen" of Loestrin 1/20, and a 1989 letter revealing that Mr. Boissonneault (and Mr. Reichel) knew about other extended regimens. PSOF ¶¶ 12, 23 n.60, 39. This evidence could allow a jury to conclude that Warner Chilcott knew about this fraud when it enforced the patent.

Lastly, Defendants' argument that Loestrin 1/20 is immaterial to patentability is similarly unpersuasive. They argue that the patent examiner did not find Mr. Meilman's arguments about breakthrough bleeding persuasive. They also claim the Loestrin 1/20 Reference is cumulative of other non-commercialized prior art references with less than 30 mcg of EE. But Plaintiffs underscore that the examiner was told that the invention involved a new combination oral contraceptive with ultra-low doses of estrogen that reduced breakthrough bleeding. Pls.' Opp'n to Summ. J. 8. A reasonable jury could conclude that the applicant's failure to cite Loestrin 1/20 as prior art — along with Mr. Meilman's assertions arguably directing the examiner away from it – evinces that the patent would not have issued had the examiner known about Loestrin 1/20.

In sum, Defendants are not entitled to summary judgment on Plaintiffs' Walker Process fraud claim.

3. Sham Litigation

Defendants similarly challenge Plaintiffs' sham litigation claims. Sham litigation is actionable where "patent infringement litigation was 'a mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor.'" United Food & Commercial Workers Unions & Emp'rs Midwest Health Benefits Fund v. Novartis Pharm. Corp., 902 F.3d 1, 13 (1st Cir. 2018) ("United Food II") (quoting

E. R. R. Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127, 144 (1961)) (emphasis in original). Like Walker Process fraud, a sham "suit to enforce intellectual property rights" leads to a loss of Noerr-Pennington immunity from antitrust scrutiny. Id.

A sham litigation claim requires a plaintiff to proffer proof that the patent suits were both objectively and subjectively baseless: (1) "the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits"; and (2) the litigant subjectively understood the lawsuit to be baseless and attempted to interfere directly with competition. Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., 508 U.S. 49, 60–61 (1993) ("PRE"); In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class, 868 F.3d 132, 149 (3d Cir. 2017), judgment entered sub nom. In re Wellbutrin XL Antitrust Litig., No. 15-2875, 2017 WL 3529114 (3d Cir. Aug. 9, 2017) ("Wellbutrin XL II") ("[A]n infringement suit filed in response to an ANDA with a paragraph IV certification could only be objectively baseless if no reasonable person could disagree with the assertions of noninfringement or invalidity in the certification."). The objective prong must be sustained by clear and convincing evidence. In re Relafen Antitrust Litig., 360 F. Supp. 2d 166, 179 (D. Mass. 2005). A factfinder only addresses

subjective motivation after first evaluating objective baselessness. PRE, 508 U.S. at 60.

Plaintiffs allege Warner Chilcott's patent infringement suits against Watson, Lupin, and Mylan were "sham" suits because no reasonable person could disagree with their assertions of noninfringement or invalidity. Plaintiffs' expert — Mr. Lentz — opines that Warner Chilcott had no realistic chance of winning these patent suits, and Plaintiffs cite evidence that the ´394 patent was both obvious and an invalidating public use. Defendants rebut this evidence and stress evidence they say shows that the ´394 patent was "strong"; this, they say, necessitates a holding that the suits were not objectively baseless.[20]

The question is whether a reasonable manufacturer in Warner Chilcott's position had a realistic likelihood of succeeding on the merits of the patent infringement suits. United Food II, 902 F.3d at 13. "To be sure, this is a high burden to meet; '[g]iven the presumption of patent validity and the burden on the patent

[20] Plaintiffs' expert Mr. Lentz explains that there was no realistic chance for Warner Chilcott to succeed on the patent claims — having a 10% or less chance of succeeding, and only that high to account for potential judicial error. Defendants use this opinion to say that Plaintiffs' own expert accounts for a 10% chance of success for Warner Chilcott, which is all that is needed to defeat a sham litigation claim. But Mr. Lentz said his opinion "ought not be misconstrued to suggest that, given the actual facts and a proper application of the law, Warner Chilcott had a 10% chance of winning." Expert Report of Edward T. Lentz 82 n.269, ECF No. 891-3. Only a "reasonable" litigant's "realistic" expectations are relevant. PRE, 508 U.S. at 60–61.

challenger to prove invalidity by clear and convincing evidence, it will be a rare case in which a patentee's assertion of its patent in the face of a claim of invalidity will be so unreasonable as to support a claim that the patentee has engaged in sham litigation.'" Loestrin II, 261 F. Supp. 3d at 348 (quoting Tyco Healthcare Grp. LP, 762 F.3d at 1345). And "allegations [that] merely demonstrate that [the patentee] would have been subject to a serious defense to its infringement litigation" cannot clear this hurdle. United Food II, 902 F.3d at 15.

Here, there is enough evidence for the jury to conclude that Warner Chilcott was "less than objectively reasonable in acting on that technical act of infringement[.]" Wellbutrin XL II, 868 F.3d at 149. This includes Plaintiffs' evidence suggesting the patent was fraudulently procured and that Warner Chilcott enforced it despite that knowledge, as well as expert testimony. In light of this evidence, a reasonable juror could conclude by clear and convincing evidence that no reasonable pharmaceutical manufacturer in Warner Chilcott's position could have believed that it would succeed in litigating the ´394 patent with knowledge that it had been fraudulently procured. See In re AndroGel Antitrust Litig. (No. II), 888 F. Supp. 2d 1336, 1345 (N.D. Ga. 2012) ("Androgel I") (recognizing the standard is whether the patent was "so facially invalid that an objective litigant would not have attempted to enforce the patent[.]").

There is similarly sufficient evidence that the lawsuits were subjectively baseless. See PRE, 508 U.S. at 60–61. Because there is enough evidence to support Plaintiffs' Walker Process fraud claim, it follows that there is enough evidence from which a jury could find that the lawsuits were subjectively baseless. That is, if the patent was procured by fraud, a jury could find that Warner Chilcott, in enforcing it, was subjectively motivated to interfere with the business relationships of generic competitors. See PRE, 508 U.S. at 60–61. Plaintiffs' sham litigation claims therefore also survive summary judgment.

4. Sham Orange Book Listing

Defendants next pursue summary judgment on Plaintiffs' sham Orange Book listing claim. A patent holder is statutorily required to submit valid and enforceable patents for listing in the Orange Book. See 21 U.S.C. § 355(b)(1); In re Solodyn (Minocycline Hydrochloride) Antitrust Litig., No. 14–md–02503-DJC, 2015 WL 5458570, at *12 (D. Mass. Sept. 16, 2015) ("Solodyn II") (holding that listing patent in the Orange Book could not support a Section 2 claim where it was not held invalid or unenforceable). Despite this statutory obligation, an Orange Book listing may amount to a Sherman Act violation when a defendant's decision to list the patent was unreasonable. See In re Lantus Direct Purchaser Antitrust Litig., No. 16-12652-JGD, 2018 WL 6629708, at *5 (D. Mass. Oct. 24, 2018); see also Solodyn II, 2015 WL 5458570, at

*12 (holding that "listing presumptively valid patents in the Orange Book and enforcing them against infringers are not bases for an antitrust claim" (quoting In re Lipitor Antitrust Litig., No. 3:12-CV-2389-PGS, 2013 WL 4780496, at *21 (D.N.J. Sept. 5, 2013))).

Defendants argue Plaintiffs' Orange Book claim is meritless because Warner Chilcott listed the ´394 patent in the Orange Book as statutorily required after the FDA approved the Loestrin NDA. DSOF ¶ 50. Nonetheless, considering the evidence submitted to show that the patent was fraudulently procured, and that Warner Chilcott enforced it with that knowledge, a jury could find that Warner Chilcott had no reasonable basis for believing the patent was enforceable. See also Solodyn II, 2015 WL 5458570, at *11. This claim, therefore, also proceeds to trial.

5. Reverse Payments

Defendants challenge Plaintiffs' reverse payment claim against them on several grounds, including Plaintiffs' ability to prove at trial that these payments were in fact large and unjustified, and that they caused delay in generic entry.

To briefly recap, there are four at-issue components of the Watson settlement[21]: (1) the no-AG agreement; (2) the acceleration clause; (3) the Generess agreements; and (4) the Femring agreement.

[21] The parties agree that all arguments related to Lupin are now moot in light of the settlement with Lupin.

In the no-AG agreement, Warner Chilcott pledged not to launch an authorized generic of Loestrin until after Watson's first 180 days on the market, nor to license any other Loestrin generics to enter the market for at least the first six months after Watson's entry. Loestrin II, 261 F. Supp. 3d at 321; see DSOF ¶ 91. In the acceleration clause, as an insurance of sorts, Warner Chilcott agreed to accelerate Watson's entry date if a third party did in fact introduce a Loestrin generic. Id. Through the Generess agreements, Warner Chilcott awarded Watson the exclusive right to market and sell Generess Fe, a Warner Chilcott oral contraceptive; these agreements included a patent license and product supply agreement, in exchange for which Warner Chilcott was set to receive 15% of net sales until the launch of a Generess Fe generic. Id. Similarly, through the Femring agreement, Warner Chilcott agreed to pay Watson annual fees and a percentage of net sales in connection with the co-promotion of Femring, another Warner Chilcott product. Id.

Defendants first challenge whether Plaintiffs can establish the existence of a "reverse payment" at all. To this end, Defendants claim Plaintiffs must show a "large" and "unexplained" sacrifice by the patentee and a benefit to the generic firm from that sacrifice; absent both showings, the payments are not unlawful reverse payments, and a rule of reason analysis is unnecessary.

Reframed, Defendants' argument boils down to this – if they can show the deals reflect fair market value, then summary judgment is appropriate without needing to venture into a rule of reason analysis. Sadly, it is not that simple. Actavis says "the likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification." 570 U.S. at 159. As Judge Young put it, "[n]owhere . . . does the Supreme Court suggest that fair market value is a silver bullet against antitrust scrutiny[,]" In re Nexium (Esomeprazole) Antitrust Litig., 42 F. Supp. 3d 231, 263-64 (D. Mass. 2014) ("Nexium III"), rather, "establishing fair market value is just one of many possible defenses available to a [d]efendant seeking to demonstrate procompetitive justifications for a reverse payment." Id. at 263; King Drug Co. of Florence, Inc. v. Cephalon, Inc., 88 F. Supp. 3d 402, 419 (E.D. Pa. 2015).

Therefore, imposing the threshold barrier Defendants suggest would run right into Actavis. While the Supreme Court left "to the lower courts the structuring of the present rule-of-reason antitrust analysis[,]" Actavis, 570 U.S. at 160, this Court will not divine a "large" and "unexplained" hurdle to the analysis. See King Drug Co. of Florence, 88 F. Supp. 3d at 413.

Beyond this first attack, Defendants make several arguments specific to each provision as applied to the rule of reason analysis. The Court will address each in turn but must first resolve the relevant Daubert motions.

a. Reverse Payment Daubert Motions

i. Plaintiffs' Motion to Exclude Opinions and Testimony of Drs. Christine S. Meyer and Mark S. Robbins Regarding Procompetitive Justifications of Reverse Payments, ECF No. 874

Plaintiffs move to exclude the opinions of Defendants' experts Drs. Meyer and Robbins related to procompetitive justifications under the rule of reason. Plaintiffs claim that, contrary to law, these experts only broadly identify procompetitive effects of the settlement agreement as a whole, instead of Warner Chilcott's individual payments to Watson.[22]

As the Court in Solodyn noted, Actavis requires Defendants to show "'that legitimate justifications are present' for settlements involving reverse payments." In re Solodyn (Minocycline Hydrochloride) Antitrust Litig., No. 14-md-02503, 2018 WL 734655, at *4 (D. Mass. Feb. 6, 2018) ("Solodyn III") (quoting Actavis, 570 U.S. at 156). In Solodyn, the plaintiffs similarly argued that the defendants' expert improperly proffered justifications

[22] The parties agree that this motion is moot as related to Drs. Meyer's and Robbins's opinions about any agreement between Warner Chilcott and Lupin.

focused "upon the settlement agreements as a whole, rather than justifying the payment itself." Id. The plaintiffs in Solodyn pressed this narrow view, but the court declined to adopt it, concluding that doing so would divorce the payments from their business context. Id.; cf. Impax, 2019 WL 1552939, at *31, 34, 35 (instructing that it is proper to look at the specific restraint — the payment in exchange for eliminating competition — not at the agreement as a whole in analyzing procompetitive justifications because "[a]n antitrust defendant cannot simply cite procompetitive benefits in the abstract, but must show that those benefits bear a 'logical nexus' to the restraint") (citation omitted). Following Solodyn, this Court similarly declines to adopt such a narrow view on procompetitive scope.

Plaintiffs next seek to preclude these experts from opining that "ruinous competition" between manufacturers is procompetitive (and not anticompetitive). They say Dr. Robbins's opinion that without the no-AG agreement the possibility that Warner Chilcott might launch an authorized generic would deter Watson from launching takes issue with competition itself. It is axiomatic that "the [r]ule of [r]eason does not support a defense based on the assumption that competition itself is unreasonable." Nat'l Collegiate Athletic Ass'n v. Bd. of Regents of Univ. of Oklahoma, 468 U.S. 85, 117 (1984) (quoting Nat'l Soc'y of Prof'l Eng'rs v.

United States, 435 U.S. 679, 696 (1978)). Plaintiffs' motion is therefore GRANTED on this basis.

Lastly, Plaintiffs argue these experts improperly cite effects outside the relevant market, challenging Drs. Meyer's and Robbins's opinions that the Generess and Femring agreements benefited consumers of those products. Of course, the relevant market is something the jury will decide. For purposes of this motion, Plaintiffs use the same market they argued for market power – Loestrin, Minastrin, and their generic equivalents[23] – and underscore that the procompetitive justifications must be in the same market as the anticompetitive effects.

To suggest such a limitation, Plaintiffs cite the First Circuit's well-known football case, Sullivan v. Nat'l Football League, 34 F.3d 1091, 1113 (1st Cir. 1994). Notably, in Solodyn, the court held that it was not "persuaded that the range of procompetitive justifications contemplated in Actavis is so limited to require excluding a theory limiting procompetitive benefits to one market." Solodyn III, 2018 WL 734655, at *5. This Court again agrees with Solodyn; the oral contraceptive market – whether the jury defines it narrowly or broadly – is different from the National Football League, and it would be far too limiting to confine Defendants in this way. Actavis does not mandate this,

[23] The Retailers allege a more limited market, including only Loestrin and its generic equivalent.

and to do so would unfairly weigh the rule of reason analysis in Plaintiffs' favor.

Plaintiffs' Motion to Exclude Opinions and Testimony of Drs. Christine S. Meyer and Mark S. Robbins Regarding Procompetitive Justifications of Reverse Payments, ECF No. 874, is therefore GRANTED IN PART AND DENIED IN PART. It is GRANTED to the extent the experts opine that "ruinous competition" is procompetitive, but it is otherwise DENIED.

ii. Plaintiffs' Motion to Exclude the Expert Testimony of Dr. Louis Berneman, Philip Green, and Dr. Christine Meyer Regarding "Fair Value", ECF No. 902

Plaintiffs also move to exclude Defendants' experts' – Drs. Berneman and Meyer, and Mr. Green – opinions on "fair value". In this motion, Plaintiffs challenge two sets of opinions: (1) opinions about whether Warner Chilcott paid "fair value" to Watson for the Femring and Generess agreements because "fair value", in the way these experts use the term, conflicts with established industry standards and Actavis; and (2) Dr. Berneman's opinions and testimony as to knowledge and state of mind.

Taking the second issue first, Defendants maintain that Dr. Berneman does not opine on knowledge or state of mind, and instead simply recites relevant documents and witness testimony to provide background information. No expert will be permitted to opine on

the intentions, motives, or state of mind of any corporation. If Dr. Berneman does so, Plaintiffs' motion is GRANTED.

Moving to the parties' dispute regarding "fair value". Plaintiffs contend that Defendants' experts fail to measure the agreements against an objective standard like "market value". Defendants respond that Actavis requires a "fair value" analysis, not a "market value" analysis, and, going one step further, "fair value" is satisfied if the agreement made strategic business sense for Warner Chilcott. Defendants thus reduce "fair value" to a question of "whether [Warner Chilcott] did or did not go 'out of pocket' in respect of the business agreements at issue." Defs.' Opp'n to Pls.' Mot. to Exclude Expert Testimony of Dr. Louis Berneman, Philip Green, and Dr. Christine Meyer Regarding "Fair Value" ("Defs.' Opp'n to Exclude Berneman, Green, and Meyer") 14, ECF No. 1031 (citing Actavis, 570 U.S. at 157). Said another way, Defendants believe a fair value agreement is one in which the patentee received back at least as much as it paid.

The Court disagrees with both interpretations. As explained above, Actavis makes clear that the reverse payment macrocosm concerns whether the patentee sought to induce a generic challenger to abandon its claim for a share of the monopoly profits. See Actavis, 570 U.S. at 154. In evaluating the division of monopoly profits, the factfinder may consider patentee profits, but the fact that the patentee profited cannot conclusively answer whether

the agreement was for fair value. Thus, to the extent that Defendants' experts opine that the agreements were for "fair value" because Warner Chilcott received a profit, those opinions are excluded. But that does not end the inquiry.

If Defendants had their way, "fair value" would not allow any inquiry into market value, especially here, where Defendants submit that there is no readily available market against which an expert could conduct a market-based valuation. Defendants overstate that "an agreement that is consistent with the market that also makes strategic business sense for Warner Chilcott can be nothing less than fair value." Defs.' Opp'n to Exclude Berneman, Green, and Meyer 4. But Plaintiffs similarly overstate that only a market-based analysis can answer this important question. These extreme positions ignore that market value can be a component of the fair value inquiry.

Plaintiffs' Motion to Exclude the Expert Testimony of Dr. Louis Berneman, Philip Green, and Dr. Christine Meyer Regarding "Fair Value", ECF No. 902, is GRANTED IN PART AND DENIED IN PART. It is GRANTED if Dr. Berneman seeks to opine on intent, motive, or state of mind, and to the extent that the experts opine that the

agreements were for "fair value" because Warner Chilcott received a profit, but is otherwise DENIED.[24]

iii. Defendants' Motion to Exclude the Opinions and Testimony of John R. Tupman, ECF No. 892

Defendants next move to exclude the opinions of John Tupman, arguing that Mr. Tupman, a former Eli Lilly executive, is unqualified to opine on the "fair value" of the Femring and Generess agreements. Mr. Tupman offers the opinion that neither the Femring nor the Generess agreements were for "fair value" because the parties did not conduct the customary investigation or due diligence. Defendants insist his opinions lack an objective, published, or reliable methodology and that his experience at a large pharmaceutical company cannot support his conclusions.

Plaintiffs offer various reasons why Mr. Tupman's experience qualifies him to offer his opinions. In Solodyn, the court allowed Mr. Tupman's opinions and testimony based largely on the same grounds advanced here. Solodyn III, 2018 WL 734655, at *3. The Court is convinced that Defendants' arguments go to the weight of Mr. Tupman's opinions, not their reliability, and can be addressed on cross-examination.

[24] The parties agree that this motion is moot as it relates to Dr. Berneman's opinions about any agreement between Warner Chilcott and Lupin.

Defendants also take issue with Mr. Tupman's opinions about what constitutes "typical" investigation or due diligence, claiming that these opinions are irrelevant to Actavis's fair value analysis. To the contrary, for a variety of reasons, a jury could find the extent of Defendants' due diligence relevant to the fair value issue, so Defendants' Motion to Exclude Mr. Tupman's Opinions, ECF No. 892, is DENIED.

b. Specific Provisions and Agreements

With respect to the substance of the agreements, Defendants assert that the evidence, even taken in the light most favorable to Plaintiffs, entitles them to summary judgment.

To satisfy their burden in the rule of reason test, a plaintiff must demonstrate "that the alleged agreement involved the exercise of power in a relevant economic market, that this exercise had anti-competitive consequences, and that those detriments outweighed efficiencies or other economic benefits." In re Loestrin 24 Fe Antitrust Litig., 814 F.3d 538, 545 (1st Cir. 2016) ("Loestrin I") (citation omitted). After establishing market power, this is a three-step process. Loestrin II, 261 F. Supp. 3d at 329. First, the plaintiff must "'prove anticompetitive effects,' by demonstrating 'a payment for delay, or, in other words, payment to prevent the risk of competition.'" Id. (quoting King Drug Co. of Florence v. Smithkline Beecham Corp., 791 F.3d 388, 412 (3d Cir. 2015), cert. denied, 137 S.Ct. 446 (2016)).

Second, "the burden then shifts to the [d]efendants to show that a challenged payment was justified by some precompetitive objective." Id. (quoting Nexium III, 42 F. Supp. 3d at 262-63). Third, "the burden shifts back to the [p]laintiffs to establish, under the rule of reason, that the settlement is nevertheless anticompetitive on balance." Id. (quoting Nexium III, 42 F. Supp. 3d at 262-63).

For the reasons detailed below, the Court finds that there is enough evidence for a reasonable factfinder to determine a prima facie reverse payment violation occurred.

i. No-AG Agreement

Focusing first on the "no-AG" provision, Defendants claim it was nearly valueless, citing a lack of evidence that Warner Chilcott would have launched an AG in the first 180 days after generic entry. Defendants say Warner Chilcott in fact did not intend to launch an AG (and Watson did not expect them to), and it therefore gave up nothing through this agreement. Defendants also point to expert testimony that Congress was actively considering banning AGs.[25] Plaintiffs say Warner Chilcott planned an AG launch, and that agreeing not to launch an AG caused it to, "[a]t a minimum,

[25] Plaintiffs' Motion to Exclude in Part the Expert Opinions of Christine Meyer, Ph.D. and Philip Green That Authorized Generics Were Facing Legal Uncertainty, ECF No. 901, is DENIED. The opinions are relevant because they deal with a potential risk factor pertinent to determining value. The criticisms can be effectively addressed on cross-examination.

. . . [give] up freedom to launch an AG once Watson launched." Pls.' Opp'n to Summ. J. 28; see also PSOF ¶¶ 87, 88. This, Plaintiffs reply, translates to value. The Court is satisfied that this is an issue of fact for the jury.

Continuing, Defendants say the agreement was clearly justified, citing its fair value, the saved litigation costs, and other broad procompetitive justifications. Even if the no-AG agreement had some negligible value, they say, that value was less than the avoided litigation costs. Actavis recognizes that if a payment amounts to less than saved litigation costs, it may avoid antitrust scrutiny. 570 U.S. at 156 ("The reverse payment, for example, may amount to no more than a rough approximation of the litigation expenses saved through the settlement."). Here, Defendants claim Warner Chilcott gave up, at most, $1.5 million to $4.8 million, far less than the saved litigation costs. DSOF ¶ 99. Plaintiffs counter with expert calculations that the agreement meant Warner Chilcott sacrificed profits of $41.1 million,[26] conferring a $101.5 million benefit to Watson. See PSOF ¶ 99. There is a triable issue of fact here; a rational jury could conclude that the agreement's anticompetitive effects outweighed its procompetitive justifications. See Namenda I, 331 F. Supp. 3d at 199. The Court is thus satisfied that the jury will have enough

[26] The Retailers' expert, Dr. Leffler, values Warner Chilcott's sacrifice at $21.9 million. PSOF ¶ 99.

factual basis to "properly engage in a rule-of-reason analysis[.]" Nexium III, 42 F. Supp. 3d at 294.

ii. Acceleration Clause

Defendants next argue that the EPPs (the only party pursuing this theory) identify no evidence that the acceleration clause delayed generic entry. They say this paucity of evidence means a jury could not find the clause was anticompetitive where the clause in fact accelerated Watson's generic entry; Watson (through Amneal) launched a Loestrin generic three weeks earlier than the January 24, 2014 entry date. DSOF ¶ 109, 110. Defendants say the EPPs' position that the acceleration clause is anticompetitive relies purely on speculative expert testimony.

Plaintiffs admit there is no "exact quantitative dollar value" attributed to the clause. Sept. 11, 2019 Hr'g Tr. 196, ECF No. 1257. But the value, they say, is in ensuring the exclusivity that Watson forfeited. They point to their expert's conclusions that, absent the acceleration clause, generics would have entered earlier and that the clause deterred later filers, providing Watson with substantial value. PSOF ¶ 110. While Defendants claim that the undisputed, real-world facts prove that the acceleration clause accelerated Watson's entry date and led to additional competition, the Court is satisfied that a reasonable jury could consider this clause anticompetitive. See Wellbutrin XL I, 133 F. Supp. 3d at 753 (explaining that the reasonableness of reverse

payment agreements is evaluated based on the time period they were entered into, not with the benefit of hindsight).

Defendants also cite various broad procompetitive justifications for the clause. For example, in addition to potentially accelerating generic entry, Defendants use expert testimony to submit that acceleration clauses facilitate settlement. That said, these justifications do not mandate summary judgment; the Court concludes that a reasonable jury could find that the agreement's anticompetitive effects outweighed the procompetitive effects. See Namenda I, 331 F. Supp. 3d at 199.

iii. Generess Agreements

On similar grounds, Defendants challenge Plaintiffs' submission that the Generess agreements amount to reverse payments. Foundationally, Defendants claim that the Generess agreements have nothing to do with the Watson settlement. DSOF ¶ 123. To this, Plaintiffs respond with expert testimony that no reasonable branded company would enter these agreements on a standalone basis. PSOF ¶ 114. The reasonableness of the agreements is clearly a fact question; a rational juror could conclude that this agreement was part of the larger Watson settlement, and not an unrelated side deal.

Defendants next argue Warner Chilcott did not suffer any financial loss from the Generess agreements, pointing to evidence that Plaintiffs' experts attribute no value to the agreements and

that Warner Chilcott was guaranteed to make a profit. See DSOF ¶ 124. In response, Plaintiffs point to expert opinions on what they frame as a suspect lack of typical due diligence, as well as the fact that the Generess agreements required Warner Chilcott to continue its contractual relationship with Watson regardless of Watson's success. Defendants again claim these agreements were for fair value. But their assertion that "[t]o the extent that there is a 'market value' for such agreements, the agreements are consistent with over 100 other agreements and thus [reflect] market value" is hotly contested. Reply Mem. of Law in Supp. of Defs.' Mot. for Summ. J. ("Defs.' Reply") 34, ECF No. 1086. To be sure, Defendants identify several procompetitive justifications for these agreements. Resolution of this involves questions of fact, and the Court concludes that a jury could determine these agreements amounted to large and unjustified reverse payments.

iv. Femring Agreement

Finally, Defendants similarly argue the Femring agreement was not a large, unexplained reverse payment because it was a fair value agreement. DSOF ¶ 135. They claim Warner Chilcott and Watson entered into the agreement as a standalone agreement. Id. As with the Generess agreements, Plaintiffs rebut this with expert opinions that no reasonable branded pharmaceutical company would enter into this agreement as a standalone deal. This too is an issue of fact for the jury.

As to the agreement's value, Defendants argue Warner Chilcott forecasted that it would realize $21.2 million more from the agreement than without it, and that it made good business sense for various other reasons, including building brand awareness. Id. ¶ 130. Plaintiffs' expert counters that "the fair value of the services that Watson was to provide under [the agreement] was only $4.8 million – $21.6 million less than Warner Chilcott forecast it would pay Watson." Pls.' Opp'n to Summ. J. 30. Whether this agreement was for fair value is a question of fact for the jury and, on balance, the jury could determine that the anticompetitive effects outweighed Defendants' proffered procompetitive justifications.

v. Entire Settlement

Along with evaluation of the agreements individually, the settlement must be considered holistically to determine its alleged effect on competition. See Aggrenox I, 94 F. Supp. 3d at 243 ("A settlement agreement may be very simple or tremendously complex, and it may involve all manner of consideration; and if, when viewed holistically, it effects a large and unexplained net transfer of value from the patent-holder to the alleged patent-infringer, it may fairly be called a reverse-payment settlement."); see also In re Opana ER Antitrust Litig., 162 F. Supp. 3d 704, 718 (N.D. Ill. 2016) (declining the defendants' invitation to assess the components of the settlement in a

"piecemeal fashion" to determine whether "each individual payment fails to rise to the level of a large and unjustified payment" and choosing instead to "determine whether, when taken as a whole, the total payment . . . was large and unjustified"); In re Niaspan Antitrust Litig., 42 F. Supp. 3d 735, 752 (E.D. Pa. 2014) (recognizing the agreements may not be "dismember[ed]" and instead should be read as a whole).

Having determined Plaintiffs' evidence could support a finding that each individual agreement and provision was a component of a larger settlement and could constitute a violation, the next question is whether, when considered holistically, "the entire deal, taken as a whole, amounted to a large and unjustified reverse payment." Loestrin II, 261 F. Supp. 3d at 331. The Court is satisfied the jury could find this to be true. For one, Plaintiffs submit expert testimony to support their claim that "the value far exceeds the estimated $9.3 million in litigation costs that Warner Chilcott avoided by settling." Pls.' Opp'n to Summ. J. 34. For this reason, and those discussed above, the Court holds that Plaintiffs have offered sufficient evidence from which a reasonable juror could find that Warner Chilcott's payments to Watson "did not merely compensate [it] for avoided litigation costs or fair value for services – and thus were [a] large and unjustified reverse payment in violation of the antitrust laws." Namenda I, 331 F. Supp. 3d at 196.

c. Causation

Yet, demonstrating that a jury could find a violation does not end Plaintiffs' battle; Plaintiffs must also point to evidence that these violations caused Watson to delay Loestrin generic entry. See Wellbutrin XL II, 868 F.3d at 164-65.

"In an antitrust case, plaintiffs must demonstrate that the antitrust violation was a material cause of their injury." Solodyn I, 2018 WL 563144, at *13 (internal citation omitted). Defendants say Plaintiffs fail to present any evidence showing that reverse payments delayed Loestrin generic entry, requiring summary judgment in Defendants' favor. Defendants have a high bar to meet, because causation is generally a question best left for the jury. Id. (citing Bigelow v. RKO Radio Pictures, Inc., 327 U.S. 251, 264 (1946)).

Plaintiffs advance three causation theories: absent the reverse payments, (1) Warner Chilcott and Watson would have entered into an earlier negotiated alternative no-payment entry date; (2) Watson would have launched "at risk" before the conclusion of the patent litigation; and (3) Watson would have won the patent litigation, obtaining a final, unappealable judgment. To defeat summary judgment, Plaintiffs must show an issue of material fact as to one or more of these theories. See Peckham v. Cont'l Cas. Ins. Co., 895 F.2d 830, 837 (1st Cir. 1990).

First, Defendants claim there is no evidence that the no-AG agreement, the Generess agreements, or the Femring agreement caused Watson to agree to a later entry date; that Dr. McGuire admitted that there is no evidence that these agreements were necessary to settle the patent litigation, and instead Watson would have agreed to the settlement even without these deals; and that Warner Chilcott and Watson reported their settlement to the appropriate agency, as required by the Hatch-Waxman Act. Defendants say this makes it implausible that these agreements were "one-sided, anticompetitive business deals[.]" Defs.' Mem. in Supp. of Mot. for Summ. J. ("Defs.' Mot. Summ. J.") 46-47, ECF No. 859. Tackling this initial defense requires deciding Defendants' Motion to Exclude the Opinions and Testimony of Plaintiffs' Expert Dr. Thomas McGuire.

i. Defendants' Motion to Exclude Opinions and Testimony of Plaintiffs' Expert Dr. Thomas McGuire, ECF No. 882

Dr. McGuire is a seasoned professor of health economics, and Defendants move to exclude his opinions on several grounds. First, they argue that Dr. McGuire relies on an unpublished, untested, and unaccepted theory "to second-guess the bargained-for entry date for the reverse payment" with his "alternative entry date" test. Defs.' Mem. of Law in Supp. of Mot. to Exclude Opinions and Testimony of Pls.' Expert Dr. Thomas McGuire ("Defs.' Mot. to Exclude McGuire") 1, ECF No. 944. In formulating his opinion, Dr.

McGuire used forecasting documents from Warner Chilcott and Watson to determine the earliest and latest date, respectively, that Warner Chilcott and Watson would have agreed to entry without the reverse payment. The same argument was made in Asacol, and this Court agrees with Judge Casper that, "[t]he fact that [Dr.] McGuire's theory has not yet been published is not alone grounds for its exclusion at trial." In re Asacol Antitrust Litig., 323 F.R.D. 451, 474 (D. Mass. 2017) ("Asacol I"), rev'd on other grounds by In re Asacol Antitrust Litig., 907 F.3d 42 (1st Cir. 2018).

Defendants further argue that Dr. McGuire relies uncritically on an assumption provided by counsel that Watson had a 90% chance of success in the patent litigation. While Plaintiffs respond that Dr. McGuire's methodology was accepted in Solodyn, Defendants attempt to distinguish that case by arguing that in Solodyn Dr. McGuire relied on an assumption from another expert, not from counsel. Here, too, it is clear that Dr. McGuire relies on Plaintiffs' expert Mr. Lentz; excluding Dr. McGuire's opinion because counsel supplied him with that expert-based assumption would elevate form over substance.

Second, Defendants claim that Dr. McGuire relies on an unpublished, untested, and unaccepted theory "to second-guess new product innovation" through his "profit sacrifice" test. Defs.' Mot. to Exclude McGuire 1. Using this test, Dr. McGuire opines

that Warner Chilcott expected to lose patients, sales, and profits as a result of the product hop to Minastrin. Based on that, he concludes this sacrifice of profits only makes sense if Warner Chilcott's goal was to suppress generic Loestrin competition. Defendants argue that the "profit sacrifice" test, on top of being unpublished and untested, is fundamentally unreliable because it has no limiting principle – under this model, almost every new product launch is anticompetitive. Other courts have accepted this test in spite of it being unpublished. See Asacol I, 323 F.R.D. at 474. As for Defendants' argument that it lacks a limiting principle, "this type of objection goes to the weight, rather than admissibility, of [Dr.] McGuire's testimony, and can be raised before a fact-finder in cross-examination." Id.

Third, Defendants argue that Dr. McGuire skipped over the required rule of reason analysis by relying uncritically on Mr. Lentz's assumptions (through counsel). Plaintiffs say no, Dr. McGuire did analyze Defendants' proffered procompetitive effects, and ultimately rejected them. Plaintiffs' submission is supported by the record evidence. Further, as was the case in Asacol, "the presence of any procompetitive benefits . . . is a disputed issue of material fact[.]" Asacol I, 323 F.R.D. at 474. Defendants may certainly address this issue on cross-examination of Dr. McGuire, but it is not a basis to exclude his opinion.

Fourth, Defendants contend that Dr. McGuire's methodologies lead to absurd results. For instance, they say, Dr. McGuire improperly attributes the vast majority (over 80%) of the no-AG clause's value to sales made after the six-month exclusion period, despite the fact that Warner Chilcott was free to enter at that point. This again is fodder for cross-examination, not a basis for exclusion.

Fifth, Defendants maintain that Dr. McGuire does not model Warner Chilcott's or Watson's legitimate business considerations in the patent settlement negotiations. This also does not render Dr. McGuire's opinion unreliable and excludable, and instead may be addressed on cross-examination.

Sixth, Defendants argue that Dr. McGuire improperly opines on issues of patent law and PTO procedures. Defendants point to the section in Dr. McGuire's report in which he discusses allegedly "Weak or Improperly Listed Patents", and includes commentary that "[o]verworked patent examiners may fail to screen out some useless or otherwise invalid applications." Defs.' Mot. to Exclude McGuire 10-11. Plaintiffs brush this off as Dr. McGuire providing background on the PTO without opining on the validity of patents or offering a legal conclusion. Dr. McGuire clearly is not qualified to opine on patent law or PTO procedure, or to offer opinions based in speculation as to the patent examiners' workloads or reasoning, and Defendants' motion is GRANTED on this point.

In sum, Defendants' Motion to Exclude Certain of Dr. McGuire's Opinions, ECF No. 882, is GRANTED IN PART AND DENIED IN PART; the motion is GRANTED to the extent he opines on matters of patent law or PTO procedures, or otherwise improperly speculates about the patent examiner's state of mind. The motion is otherwise DENIED.

Having done all the necessary groundwork, the Court now addresses Defendants' substantive challenges to Plaintiffs' causation theories.

ii. Alternative Settlement with an Earlier Entry Date

Plaintiffs' first causation theory is that, but for the reverse payments, Warner Chilcott and Watson would have settled the patent suit with an earlier generic entry date. Plaintiffs' experts, Drs. McGuire and Leffler, opine that it would have made economic sense to settle with an entry date earlier than January 22, 2014, because, in part, Watson's earlier generic entry (and resulting lucrative profits) would obviate the need for Warner Chilcott to pay Watson to settle. Here, Defendants essentially reargue their unsuccessful criticism of Dr. McGuire's opinions. Their similar qualms about Dr. Leffler's opinions are not grounds for exclusion and are appropriate for cross-examination.[27]

[27] Despite citing multiple grounds to justify his exclusion, Defendants actually never moved to exclude Dr. Leffler's opinions. To the extent their argument may be read as a motion, it is denied.

While this evidence by itself creates a triable issue, Defendants separately criticize these expert opinions by arguing that the undisputed, real-world conduct of the generic manufacturers defeats the theory that the ´394 patent was invalid. Therefore, they say Plaintiffs' experts may not soundly rely on Mr. Lentz's opinion that Watson had a 90% chance of success in the litigation. They cite evidence that only three companies ever filed ANDAs challenging the patent and that Schering/Bayer paid Warner Chilcott a large sum of money to license the patent. They insist a weak patent would have invited more ANDA filings.

The behavior of generic manufacturers may be relevant evidence for the jury to consider, but it does not warrant summary judgment. Watson executives may testify that Warner Chilcott never offered Watson an entry date earlier than January 22, 2014, and Plaintiffs' experts may respond that Watson would have sought the earliest entry date possible. PSOF ¶ 94. What is more, similar theories have survived summary judgment in similar cases; and the theory survives here as well. See, e.g., Solodyn I, 2018 WL 563144, at *21-23; Namenda I, 331 F. Supp. 3d at 172-74, 199-202; United Food & Commercial Works Local 1776 v. Teikoku Pharma USA, 296 F. Supp. 3d 1142, 1186-90 (N.D. Cal. 2017) ("Lidoderm").

iii. Launching Generic Loestrin "At Risk"

Plaintiffs' second causation theory is that, but for the settlement, Watson would have launched generic Loestrin "at risk"

on or before September 9, 2009 (the date that Watson received final FDA approval to sell its generic).[28] Defendants argue there is no evidence to back up this theory and it relies on mere guesswork, so summary judgment is appropriate.

Of course, Plaintiffs must submit evidence from which a rational jury could find that Watson would have entered earlier without these agreements. But, in addition, this theory requires Plaintiffs to prove that Watson could have launched at risk "lawfully" – that is, without infringing a lawful patent. See Solodyn I, 2018 WL 563144, at *13; see also In re Nexium (Esomeprazole) Antitrust Litig., 842 F.3d 34, 62-63 (1st Cir. 2016) ("Nexium II"). Otherwise, the patent acts as "an independent regulatory bar" to Watson's at-risk launch. Nexium II, 842 F.3d at 63. If the patent was valid, or if Watson infringed the patent, then, as Defendants point out, Watson would have "expos[ed] itself to massive damages to Warner [Chilcott] if it lost." Defs.' Mot. Summ. J. 30.

So, "[d]o the parties need to accomplish . . . the turducken task of litigating a patent case within an antitrust case about the settlement of the patent case?" In re Androgel Antitrust

[28] "In the context of patent litigation, a launch is said to be 'at-risk' if it takes place before the questions of infringement and validity are resolved, either through litigation or a license." Wellbutrin XL II, 868 F.3d at 168 n.59.

Litig. (No. II), No. 1:09-CV-955-TWT, 2018 WL 2984873, at *13 (N.D. Ga. June 14, 2018) ("Androgel II") (internal citations omitted). Not exactly. To be sure, Plaintiffs must produce "some evidence" of patent invalidity or noninfringement. Solodyn I, 2018 WL 563144, at *13; see also Wellbutrin XL I, 133 F. Supp. 3d at 764 ("The existence of a valid and uninfringed patent would interfere with the plaintiffs' chain of causation: a valid patent independently precludes competition apart from any agreement and an 'at risk' launch is unlawful absent a later finding of patent invalidity or non[]infringement.") (citation and alterations omitted). While the parties dispute what this acknowledged "some evidence" entails, the Court agrees with Plaintiffs that they need "some evidence" that Watson could have won the patent suit.

Defendants cite Nexium to say Plaintiffs must introduce "some evidence" that Watson would have won the patent suit. Nexium II, 842 F.3d at 63. Plaintiffs rely on Lidoderm and Solodyn to respond that they must only proffer "some evidence" that Watson could have won the patent suit; Lidoderm, followed by Solodyn, considered Nexium, and departed from it only to adhere faithfully to Actavis. Solodyn I, 2018 WL 563144, at *14; Lidoderm, 296 F. Supp. 3d at 1154-55; see also Actavis, 570 U.S. at 157 ("[I]t is normally not necessary to litigate patent validity to answer the antitrust question (unless, perhaps, to determine whether the patent litigation is a sham)."). Thus, the Court agrees for this

probabilistic theory Plaintiffs must submit "some evidence" that the generic could have won the patent suit. See Lidoderm, 296 F. Supp. 3d at 1155 (considering Nexium and reasoning that "'[s]ome evidence' is not the same as requiring plaintiffs to prove that the generic defendant would have won, only that it could have") (emphasis in original); see also Solodyn I, 2018 WL 563144, at *14 (following Lidoderm). But see Androgel II, 2018 WL 2984873, at *14 n.108 (considering this standard "inappropriate because evidence that the Generics could have won gets us no closer than we are now to answering the question of whether the Generics would have been able to enter the market in a but-for world, or if a valid patent would have prevented them") (emphasis in original).

Plaintiffs readily meet this benchmark. In Warner Chilcott's patent suit against Watson, Watson had the burden to prove invalidity of the ´394 patent with clear and convincing evidence. See Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 254 (1986). Plaintiffs must therefore submit some evidence from which a reasonable jury could determine that Watson could have won the patent litigation. Solodyn I, 2018 WL 563144, at *14. The Court is satisfied that they have. Plaintiffs' expert – Mr. Lentz – opines that Watson had a 90% chance of success in the patent litigation. While Defendants, in addition to reiterating their criticisms of Mr. Lentz, make several arguments to show Warner

Chilcott would have succeeded in the patent suit, the Court has already addressed each for Walker Process fraud. None call for summary judgment.

In addition, this causation theory requires evidence of Watson's willingness to launch at risk, and Defendants say Watson clearly had no intention to do so. Solodyn I, 2018 WL 563144, at *19; DSOF ¶ 105. Again, Plaintiffs point to Mr. Lentz's opinion on Watson's chance of success, as well as internal forecasts, evidence that Watson had completed launch planning activities for a February 2009 launch, and evidence of Watson's high tolerance for and history of risk taking. PSOF ¶ 105. Plaintiffs' evidence also suggests both Warner Chilcott and market observers considered that Watson may have launched at risk. Id. In response, Defendants dispute Plaintiffs' interpretation of this evidence, point to contradictory statements from Watson executives, and argue that this theory relies mainly on unsupported, speculative expert opinions. But these expert opinions survived their Daubert challenges, and the rest of Defendants' concerns only demonstrate issues of fact. Making all reasonable inferences in Plaintiffs' favor, summary judgment is unwarranted.

iv. Final Unappealable Judgment

Plaintiffs' third and final causation theory claims that Watson would have launched on August 1, 2011, after securing a final unappealable judgment in its favor. To succeed on this

theory, Plaintiffs must prove that Watson would have prevailed on any issue in the underlying case: noninfringement, invalidity, or unenforceability due to inequitable conduct. Solodyn I, 2018 WL 563144, at *14-18. In that case, Watson needed to prove the latter two theories by clear and convincing evidence. See Microsoft Corp. v. i4i Ltd. P'ship, 564 U.S. 91, 95 (2011); Therasense, 649 F.3d at 1290. To survive summary judgment, Plaintiffs must produce evidence from which a reasonable jury could find that Watson would have succeeded on at least one of these three theories.

Defendants say Warner Chilcott clearly would have prevailed on its claim that Watson infringed the ´394 patent. They say Mr. Lentz's opinion about Watson's infringement vel non hinges on Watson's ability to prove reduced incidence of breakthrough bleeding was a claim limitation of the patent. While Defendants again point to the Mylan Markman decision to say this is indisputable, the Court has already held that that decision is not conclusive evidence here. This is an issue of fact for the jury.

Defendants also argue Plaintiffs would not succeed on their claims of invalidity and inequitable conduct where the sole evidence in support of Plaintiffs' claims relates to Loestrin 1/20, the 30-Woman Study, and the Molloy Article. While Defendants repeat their arguments as to these issues, the Court has determined that two of the three theories may proceed. In any event,

Plaintiffs have submitted expert opinions on this theory, and thus clearly meet their burden.

6. Product Hop

Defendants claim they are entitled to summary judgment on Plaintiffs' product hop claim, arguing the evidence does not support a finding that Warner Chilcott's decision to launch Minastrin and cease manufacturing Loestrin coerced patients to switch from Loestrin to Minastrin.

The law surrounding product hop condemns actions taken by brand-name drug manufacturers "to prevent pharmacists from substituting a generic equivalent when presented with a prescription for the newly modified brand-name drug." In re Asacol Antitrust Litig., 15-cv-12730-DJC, 2016 WL 4083333, at *2 (D. Mass. July 20, 2016) ("Asacol II"); see New York ex rel. Schneiderman v. Actavis PLC, 787 F.3d 638, 643 (2d Cir. 2015) ("Namenda II") (acknowledging conduct sufficient to violate the Sherman Act is "conduct by a monopolist to perpetuate patent exclusivity through successive products"); In re Suboxone (Buprenorphine Hydrochloride and Nalaxone) Antitrust Litig., No. 13-md-2445, 2019 WL 4735520, at *1 (E.D. Pa. Sept. 27, 2019) ("Suboxone I"). One example of this conduct is a so-called "hard switch", in which the brand-name drug manufacturer removes (effectively or literally) the branded drug from the market before patent expiry "to deprive potential generic manufacturers a

prescription base for their generic drugs." Asacol II, 2016 WL 4083333, at *2; see also Namenda II, 787 F.3d at 648, 654.

In accordance with Section 2 of the Sherman Act, to succeed Plaintiffs must prove (1) Warner Chilcott had monopoly power in the relevant market; and (2) it "has acquired or maintained that power by improper means." Town of Concord v. Boston Edison Co., 915 F.2d 17, 21 (1st Cir. 1990) (quoting Grinnell Corp., 384 U.S. at 570–71). "Improper means", also known as "exclusionary conduct", is "conduct, other than competition on the merits or restraints reasonably necessary to competition on the merits, that reasonably appears capable of making a significant contribution to creating or maintaining monopoly power." In re Asacol Antitrust Litig., 233 F. Supp. 3d 247, 266-67 (D. Mass. 2017) ("Asacol III") (quoting Boston Edison Co., 915 F.2d at 21) (quotation marks omitted); see also Solodyn II, 2015 WL 5458570, at *10. Notably, "product introduction alone 'does not violate Section 2 even if it is performed by a monopolist and harms competitors as a result.'" Asacol III, 233 F. Supp. 3d at 268 (quoting Allied Orthopedic Appliances Inc. v. Tyco Health Care Grp. LP, 592 F.3d 991, 998-1000 (9th Cir. 2010)); Namenda II, 787 F.3d at 652 (recognizing courts are directed to view with a skeptical eye "claims that competition has been harmed by a dominant firm's product design changes")(quoting United States v. Microsoft Corp., 253 F.3d 34, 65 (D.C. Cir. 2001)). These claims are analyzed under the rule of

reason. Loestrin II, 261 F. Supp. 3d at 350 & n.33 (explaining that product hop claims are analyzed under the rule of reason, meaning Plaintiffs must submit sufficient evidence to show anticompetitive conduct and to rebut Defendants' procompetitive justifications).

Before addressing the merits of this claim, the Court tackles Plaintiffs' Motion to Exclude the Opinions of Drs. Meyer, Robbins, and Schilling.[29]

a. Plaintiffs' Motion to Exclude Opinions and Testimony of Drs. Christine S. Meyer, Mark S. Robbins, and Melissa A. Schilling Regarding Lack of Anticompetitive Effect from Product Hop, ECF No. 875

In the first instance, Plaintiffs challenge the opinions of Drs. Meyer, Robbins, and Schilling to the extent they opine that the following fact reveals no anticompetitive effect: "[i]n July 2013 there were 365,449 prescriptions filled at pharmacies for Loestrin 24" and "by the time Loestrin 24 generics entered the market in January 2014, there were only 5,742 prescriptions for Loestrin 24 available for generic substitution." Pls.' Mem. of Law in Supp. of Mot. to Exclude Opinions and Testimony of Drs. Meyer, Robbins, and Schilling Regarding Lack of Anticompetitive

[29] Since the filing of this motion, Plaintiffs effectively dismantled this Daubert motion and refiled it in the form of a string of motions in limine. Plaintiffs never withdrew this motion, so the Court rules on it now consistent with its already-issued rulings on the motions in limine, if only to provide more detail.

Effect from Product Hop ("Pls.' Mot. to Exclude Meyer, Robbins, and Schilling") 1, ECF No. 940. Plaintiffs say these experts' opinions are nothing more than ipse dixit. But really, Plaintiffs protest far too much – in effect, they simply argue the obverse: that hard switching before generic entry is necessarily anticompetitive.[30] As discussed below, while hard switching before generic entry may be anticompetitive, it is not necessarily so in every case; a hard switch may be anticompetitive if the brand manufacturer utilizes coercive means to effectuate it. To the extent that Defendants' experts state the law differently, including opining on what the law should be, those opinions are excluded.

Next, Plaintiffs argue that Dr. Meyer improperly opines that Warner Chilcott's conduct was not anticompetitive, where it did not employ tactics other manufacturers use to deplete the branded drug supply; these tactics include recalling products in the supply chain, removing the brand product listing from the Orange Book, and falsely disparaging the safety or efficacy of the brand product. These facts are relevant and Dr. Meyer may discuss them. That said, Dr. Meyer may not opine that the non-existence of these tactics means no hard switch occurred as a matter of law.

[30] Plaintiffs claim these experts, in relying on Doryx, effectively ignore this Court's ruling on Defendants' Motion to Dismiss. But the Court neither adopted Namenda over Doryx, nor considers these cases legally irreconcilable.

Plaintiffs next posit that Dr. Meyer errs in failing to examine the alleged product hop's effects in the market of branded and generic Loestrin and Minastrin, the product market defined by Plaintiffs. Plaintiffs admit that, if the market extends beyond that,[31] "they lose regardless of whether Warner Chilcott's conduct was otherwise unlawful." Pls.' Mot. to Exclude Meyer, Robbins, and Schilling 6. First, Plaintiffs' concession renders any expert's analysis beyond that market irrelevant. Second, as the Court has held, the existence of monopoly power, including the relevant market definition, is an issue of fact for the jury.[32] Plaintiffs' Motion to Exclude Drs. Meyer, Robbins, and Schilling, ECF No. 875, is GRANTED IN PART AND DENIED IN PART. The motion is

[31] The DPPs and the EPPs allege the relevant market consists of Loestrin, Minastrin, and their generic equivalents; the Retailers allege the relevant market consists of only Loestrin and its generic equivalents.

[32] Plaintiffs also argue that Dr. Meyer's opinion rests on an unreliable methodology because her conclusion relies only on the fact that generic Loestrin products eventually entered the market. The Court has already held that total foreclosure from the market is not required for a finding of anticompetitive conduct. Loestrin II, 261 F. Supp. 3d at 351; see also Abbott Labs. v. Teva Pharm. USA, Inc., 432 F. Supp. 2d 408, 423 (D. Del. 2006). To the extent that Dr. Meyer opines that Warner Chilcott's conduct was not anticompetitive absent total foreclosure, her opinion is excluded as contrary to law. Relevantly, Plaintiffs argue that Drs. Meyer and Schilling ignore the circumstances of the pharmaceutical industry, instead analogizing the facts here to that in other industries. This challenge may be addressed on cross-examination.

GRANTED to the extent that the experts attempt to recast the law as detailed above and DENIED in all other respects.

b. Merits of Product Hop Claim

On the merits, Defendants challenge whether Plaintiffs' evidence about Warner Chilcott's product redesign and roll out could support a jury finding that it coerced consumers and impeded competition.

Parroting the above Daubert motion, Defendants claim no hard switch occurred because Warner Chilcott never actively recalled or withdrew Loestrin from the supply chain, or removed Loestrin from the Orange Book, and Loestrin was available for at least some time after July 2013 (when Warner Chilcott launched Minastrin). DSOF ¶¶ 3, 192. This argument is easily snuffed out on the law. A hard switch may occur "in effect" where the branded product remains on the market in some limited fashion, see Namenda II, 787 F.3d at 648, 654, and the Court is satisfied that on this evidence a reasonable jury could find similarly here.

Defendants next submit that no anticompetitive conduct occurred because competitors – seven, to be exact – successfully entered the market with generic versions of Loestrin, eroding sales from Minastrin. This argument is likewise easily rejected; the law is clear that all that is necessary for a finding of anticompetitive conduct is that "Warner Chilcott's anticompetitive tactics succeeded in excluding would-be generic competitors from

the only cost-efficient means of distributing their products." Asacol III, 233 F. Supp. 3d at 258. That Loestrin generics eventually entered the market does not preclude a finding of anticompetitive conduct — the jury could still find that Warner Chilcott may have engaged in anticompetitive conduct by obstructing automatic generic substitution, a cost-efficient means of increasing competition. See Loestrin II, 261 F. Supp. 3d at 351 (quoting Namenda II, 787 F.3d at 656) (quotation marks omitted) ("For there to be an antitrust violation, generics need not be barred from all means of distribution if they are bar[red] . . . from the cost-efficient ones."); Abbott Labs. v. Teva Pharm. USA, Inc., 432 F. Supp. 2d 408, 423 (D. Del. 2006) ("TriCor") ("To show that conduct has an anticompetitive effect, 'it is not necessary that all competition be removed from the market. The test is not total foreclosure, but whether the challenged practices bar a substantial number of rivals or severely restrict the market's ambit.'") (quoting United States v. Dentsply Int'l, Inc., 399 F.3d 181, 191 (3d Cir. 2005)); see also In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig., 64 F. Supp. 3d 665, 683 (E.D. Pa. 2014), on reconsideration in part sub nom. In re Suboxone (Buprenorphine Hydrochloride & Nalaxone) Antitrust Litig., No. 13-MD-2445, 2015 WL 12910728 (E.D. Pa. Apr. 14, 2015) ("Suboxone II").

Defendants' final argument is their most persuasive; Defendants dispute Plaintiffs' suggestion that no showing of anticompetitive conduct is required beyond the hard switch itself. On this, the Court agrees with Defendants. It is evident from the case law that, to sustain a claim, a hard switch must be accompanied by additional evidence that Warner Chilcott's anticompetitive conduct coerced consumers to switch from Loestrin to Minastrin. See Namenda II, 787 F.3d at 654, 656 (acknowledging evidence of coercion beyond just the hard switch, including the difficulty of reverse commuting and the vulnerable population); see also Doryx, 838 F.3d at 438, 440 (affirming that the conduct evidenced a lawful soft switch, but also appreciating that "certain insignificant design or formula changes, combined with other coercive conduct, could present a closer call with respect to establishing liability"); Suboxone I, 2019 WL 4735520, at *25 (in analyzing class certification, summarizing the common question among the class as whether the defendant's "alleged product-hopping or 'hard-switch' strategy — consisting of efforts to undermine tablet sales, raise false safety concerns about tablets, withdraw branded tablets, raise branded tablet prices, and then ultimately switch the market to Suboxone film — had a 'legitimate business justification' or whether it constituted anticompetitive conduct"). Thus, Plaintiffs must identify evidence of conduct beyond the hard switch that could support a jury finding that

Warner Chilcott employed anticompetitive conduct to coerce consumers to switch from Loestrin to Minastrin.

And they do. Plaintiffs cite evidence that Warner Chilcott's so-called "[m]ission" when it launched Minastrin was to convert Loestrin users within the critical period by: implementing pharmacy pop-up notifications; sending promotional materials to doctors, patients, and pharmacies urging a switch to Minastrin because Loestrin would no longer be manufactured; implementing a patient savings program; and training sales representatives to tell doctors that a Minastrin switch "avoid[s] a lapse in therapy, and . . . ensure[s]" that patients maintain the biological integrity of their medication. ASOF ¶ 261. Warner Chilcott's intent, Plaintiffs say, was "to seamlessly transition appropriate Loestrin 24 users to Minastrin 24 Fe." Id. ¶ 261 n.66. They further analogize this case to Namenda, arguing that oral contraceptive patients have trouble reverse commuting (here, from Minastrin to generic Loestrin) and are similarly a pharmacologically vulnerable population. To be sure, Defendants quarrel with the suggestion that these facts implicate "reverse commuting".[33] True, this case is certainly not Namenda, but

[33] Defendants further distinguish Namenda to say that the coercion finding there depended, in large part, on the stipulated single-drug market definition, and the fact that undisputed evidence showed that no substitute existed outside the branded and generic drug. Namenda II, 787 F.3d at 654 n.27. Plaintiffs here also argue that the relevant market is a single-drug market. As

Namenda-style coercion is not necessarily required; the coercion question is a fact issue that will be left to the jury.

Defendants characterize the evidence to say that health care professionals chose to prescribe Minastrin and patients chose to take it. DASOF ¶ 261. And, they say, Plaintiffs' criticism of the product re-design to make the pills chewable and flavored does nothing more than "belittle" the FDA's approval of Minastrin.[34] Plaintiffs cite Namenda to respond that the "superiority" of a product cannot be a procompetitive justification because it cannot justify the withdrawal of Loestrin. Namenda II, 787 F.3d at 659. "[T]he technological desirability of the product change . . . bear[s] on the question of monopolistic intent", not the permissibility of the conduct. Id. at 653 n.25 (quoting Berkey Photo, Inc. v. Eastman Kodak Co., 603 F.2d 263, 287 n.39 (2d Cir. 1979)). Nevertheless, the Court is satisfied that this too is all fodder for the jury.

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noted above, Plaintiffs' case will rise or fall on the jury's finding as to the relevant market. If the jury agrees with Plaintiffs that it is a single-molecule market, then it will decide this question, and if not, it won't.

[34] Plaintiffs cite their expert Dr. Thomas's testimony that patients rarely expressed a problem with swallowing pills. PSOF ¶ 179. Defendants' Motion to Exclude Certain Opinions and Testimony of Michael Thomas, M.D., on Chewability and Patent Issues, ECF No. 886, is GRANTED IN PART AND DENIED IN PART; it is GRANTED to the extent that he opines on behalf of all physicians; Dr. Thomas's testimony must be limited to his own experience. The motion is otherwise DENIED.

Finally, Defendants cite the amorphous Asacol to challenge what they call Plaintiffs' "fatal gap" in their coercion evidence. They say Plaintiffs have no competent evidence of coercion to show "conduct that 'forces' a customer to make a purchase he or she did not want to make." Defs.' Mot. Summ. J. 53. The question for the jury is whether Warner Chilcott's conduct coerced patients to switch from Loestrin to Minastrin, and on this question Plaintiffs' evidence may well rise to the occasion. The Court therefore disagrees that there is a "fatal gap" in the evidence; this extension of Asacol is not one the Court is prepared to adopt.[35]

7. Damages

Defendants have repeatedly argued that lost profits, and not overcharges, is the correct measure of damages. Well-settled law readily dictates that this is wrong. See Hanover Shoe, Inc. v. United Shoe Mach. Corp., 392 U.S. 481, 494 (1968). Further, as

[35] Alternatively, Defendants ask the Court to grant summary judgment on all Plaintiffs' damages claims for purchases of brand or generic Minastrin in or after January 2014 because generic versions of Loestrin were then available to consumers and Plaintiffs have no means to identify "coerced" patients. They say the jury could not "make a 'just and reasonable' estimate of damages based on Minastrin purchases", where Plaintiffs have not submitted expert testimony or other evidence "showing which (or how many) patients who took Minastrin before generic Loestrin 24 was available . . . did so because of 'coercion.'" Defs.' Mot. Summ. J. 61-62.

In certifying the classes, the Court analyzed and approved the competing damages models, concluding that any challenges of the same could be addressed on cross-examination. None of Defendants' arguments compels revisiting that conclusion now.

this Court has already held, Defendants' quest for a reduction in damages to account for generic bypass likewise falls flat. See In re Loestrin Antitrust Litig., No. 13-2472-WES-PAS, 2019 WL 3214257, at *6 (D.R.I. July 2, 2019); see also Hanover Shoe, 392 U.S. at 494; In re Niaspan Antitrust Litig., 13–md–2460, 2015 WL 4197590, at *1 (E.D. Pa. July 9, 2015). Summary judgment is denied on this issue in light of clearly established law, and for the same reasons, Plaintiffs' Motion to Exclude Portions of Testimony of Defendants' Expert Dr. Pierre-Yves Cremieux, ECF No. 906, is GRANTED.

8. State Law Arguments

Defendants finally argue that the EPPs' state law claims are unsustainable for several reasons. None is convincing.

a. Statute of Limitations

Defendants argue that many of the EPPs' state law claims are time-barred.[36] The crux of Defendants' argument relies on their assertion that, in Plaintiffs' but-for world, Watson would have launched its Loestrin generic on September 1, 2009 (when it received FDA approval), and that any resulting harm accrued as of that date. But the law is clear that "an antitrust cause of action generally accrues 'when a defendant commits an act that injures a

[36] Plaintiffs ask this Court to consider Defendants' arguments pertaining to the state law claims waived. It declines to do so.

plaintiff's business[.]'" Aggrenox I, 94 F. Supp. 3d at 237 (quoting Zenith Radio Corp. v. Hazeltine Research, Inc., 401 U.S. 321, 338 (1971)) (emphasis in original). Here, the relevant injury occurred (and the claim accrued) not when Watson would have launched its Loestrin generic, but when a purchaser incurred an overcharge. And "each sale to the plaintiff 'starts the statutory period running again[.]'" Klehr v. A.O. Smith Corp., 521 U.S. 179, 189 (1997) (applying the continuing violation doctrine to antitrust law) (quoting 2 Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law: An Analysis of Antitrust Principles and Their Application ¶ 338b at 145 (3d. ed. 2007)); Aggrenox I, 94 F. Supp. 3d at 238 ("[A] purchaser suing a monopolist for overcharges is injured anew by each overcharge[.]").

Still, "the commission of a separate new overt act generally does not permit the plaintiff to recover for the injury caused by old overt acts outside the limitations period." Klehr, 521 U.S. at 189. Defendants ask the Court to limit Plaintiffs' claims to purchases made one to three years before April 5, 2013, when the first complaint was filed. The Court agrees. "Claims are therefore not time-barred that stem from alleged overcharges incurred within the relevant statutory period, whatever that period may be for a particular statute, measured backward from the filing of the claims." Aggrenox I, 94 F. Supp. 3d at 248.

b. Damages Prior to April 2012

Defendants finally argue that the EPPS rely on mere guesswork to calculate damages prior to April 2012. The Court has already addressed this argument and declines to address it again.[37]

III. Conclusion

For the foregoing reasons, Defendants are not entitled to summary judgment on the merits, and neither Plaintiffs nor Defendants are entitled to summary judgment on market power. Thus, Defendants' Motion for Summary Judgment Due to Lack of Market Power, ECF No. 496, is DENIED; Plaintiffs' Motion for Summary Judgment on Market Power, ECF No. 569, is DENIED; Defendants' Motion to Strike Plaintiffs' Improper Responses to Defendants' Statement of Undisputed Facts, ECF No. 610, is DENIED; Defendants' Motion to Exclude Certain Opinions and Testimony of Michael Thomas, M.D., ECF No. 640, is GRANTED IN PART AND DENIED IN PART; Defendants' Motion to Exclude the Opinions and Testimony of Plaintiffs' Expert Dr. Christopher F. Baum and Certain Opinions of Dr. Meredith Rosenthal, ECF No. 646, is DENIED; Plaintiffs' Motion to Exclude the Expert Testimony of Dr. Sumanth Addanki, ECF No. 711, is DENIED; Defendants' Motion to Exclude Certain Opinions and Testimony of Dr. Richard J. Derman, ECF No. 781, is GRANTED IN

[37] Defendants also argue the EPPs' state law claims fail for the reasons outlined in their Renewed Motion to Dismiss and Motion for Judgment on the Pleadings, ECF No. 576. This motion has been resolved, and Defendants' argument is therefore moot.

PART AND DENIED IN PART; Defendants' Motion for Summary Judgment, ECF No. 842, is DENIED; Plaintiffs' Motion to Exclude Opinions and Testimony of Drs. Christine S. Meyer and Mark S. Robbins Regarding Procompetitive Justifications of Reverse Payments, ECF No. 874, is GRANTED IN PART AND DENIED IN PART; Plaintiffs' Motion to Exclude Opinions and Testimony of Drs. Christine S. Meyer, Mark S. Robbins, and Melissa A. Schilling Regarding Lack of Anticompetitive Effect from Product Hop, ECF No. 875, is GRANTED IN PART AND DENIED IN PART; Defendants' Motion to Exclude the Opinions and Testimony of Plaintiffs' Expert Dr. Thomas McGuire, ECF No. 882, is GRANTED IN PART AND DENIED IN PART; Defendants' Motion to Exclude Certain Opinions and Testimony of Michael Thomas, M.D., on Chewability and Patent Issues, ECF No. 886, is GRANTED IN PART AND DENIED IN PART; Defendants' Motion to Exclude Certain Opinions of Edward Lentz, John Doll, and Nicholas Jewell, ECF No. 890, is GRANTED IN PART AND DENIED IN PART; Defendants' Motion to Exclude Opinions and Testimony of John R. Tupman, ECF No. 892, is DENIED; Plaintiffs' Motion to Exclude in Part the Expert Opinions of Christine Meyer, Ph.D. and Philip Green that Authorized Generics Were Facing Legal Uncertainty, ECF No. 901, is DENIED; Plaintiffs' Motion to Exclude the Expert Testimony of Dr. Louis Berneman, Philip Green, and Dr. Christine Meyer Regarding "Fair Value", ECF No. 902, is GRANTED IN PART AND DENIED IN PART; and Plaintiffs' Motion to Exclude Portions

of Testimony of Defendants' Expert Dr. Pierre-Yves Cremieux, ECF No. 906, is GRANTED.

IT IS SO ORDERED.

William E. Smith
District Judge
Date: December 17, 2019